CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 22-047 S-006, S-007, and S-008

CHEMISTRY REVIEW(S)

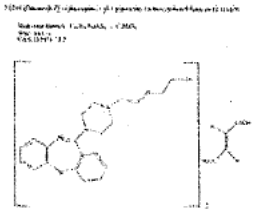
Division of Post Approval Marketing Evaluation IV
Chemist Review of Supplement

1. Division of Post Approval Marketing IV
2. NDA Number: 22047
3. Supplement Numbers/Dates: SE1- 006, 007, 008
   Letter Date: 12/17/07; 1/14/08; 1/28/08; 2/28/08; 3/27/08; 3/28/08
   Stamp Date: 12/17/07; 1/14/08; 1/28/08; 2/28/08; 3/27/08; 3/28/08
4. Amendments/Reports/Dates:
5. Received by Chemist: May 19, 2008

6. Applicant Name and Address: Astra Zeneca
1800 Concord Pike
PO BOX 8355
Wilmington DE 19803-8355

7. Name of the Drug: Seroquel XR Tablets
8. Nonproprietary name: quetiapine fumarate

9. Chemical Structure/ Chemical Name:



10: Dosage Form: Tablets
11. Potency: 50, 200, 300 and 400mg
12. Pharmacological Category: Treatment for Schizophrenia
13. How Dispensed: XXX (RX) _____(OTC)
14. Records and Reports current XXX (yes) _____(No)
15. Related IND/NDA/DMF: _____(yes) _XXX_ (No)

16. Comments and Conclusions : These bundled PA Supplements provide for a new indication for treatment of bipolar depression and mania. No new CMC information is provided in these submissions. An environmental assessment has been prepared by the Sponsor. But since the new indication does not increase the active moiety, then a request has been made for categorical exclusion under 21 CFR 25.31 (a). The environmental assessments, as submitted by the Sponsor, have been reviewed by Raanan Bloom wherein the claim for categorical exclusion is concurred. (Email to T. Bouie from R. Bloom, May 20, 2008).
Updated labeling to Dosage Forms, Description and How supplied sections of the drug insert and carton labeling, are provided, to reflect the addition of the approved 50mg extended release tablets, under the original NDA.

17. Conclusions: *This submission is for a new indication for the Seroquel® drug product. There are no changes to the CMC for the drug substance or product. The Sponsor has also decided to market the 50mg strength, previously approved under the*

original NDA. Labeling changes for the 50mg extended release tablet, are made to the Dosage, Description and How Supplied Sections, to reflect the addition of the 50mg strength.

Recommendations: Recommend Approval of this Supplement.

19. Reviewer Name Julia C. Pinto, Ph.D., Chemist

Review Notes:

Drug Product

50 mg extended-release tablets were approved under the original NDA and included in the approval letter sent by the Agency (T. Laughren, M.D. May 17, 2007). The Sponsor decided to not market this strength at the time of approval. Therefore, by this submission, the Sponsor has decided to include the 50mg strength in the labeling. It has been added to the Dosage Forms and Strength section as well as the description section and How Supplied Sections (see below).

Added to How Supplied Section:

- 50 mg Tablets (NDC 0310-0280) peach, film coated, capsule-shaped, biconvex, intagliated tablet with "SR 50" on one side and plain on the other are supplied in .bottles of 60 tablets and 500 tablets and hospital unit dose packages of 100 tablets.

Carton Label for 50mg tablets.

Evaluation: Adequate. *This submission is for a new indication for the Seroquel® drug product. There are no changes to the CMC for the drug substance or product. The Sponsor has also decided to market the 50mg strength, previously approved under the original NDA. Labeling changes for the 50mg extended release tablet, are made to the Dosage, Description and How Supplied Sections, to reflect the addition of the 50mg strength.*

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

/s/

Julia Pinto
7/7/2008 04:02:30 PM
CHEMIST

Jim Vidra
7/8/2008 12:24:33 PM
CHEMIST