EXHIBIT 40

AstraZeneca

Date: 22 June 2007

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Psychiatry
5901-B Ammendale Road
Beltsville, MD 20705-12666

RE: NDA 20-639 and NDA 22-047
SEROQUEL® (quetiapine fumarate) Tablets
Supplement-Changes Being Effected in 30 Days

Dear Sir/Madam:

In accordance with 21 CFR 314.70, AstraZeneca Pharmaceuticals LP (AstraZeneca) is submitting a Changes Being Effected in 30 Days labeling supplement for SEROQUEL (quetiapine fumarate) Tablets, NDA 20-639. AstraZeneca would also like to apply the changes in this submission to SEROQUEL XR™ (quetiapine fumarate) Extended-Release Tablets, NDA 22-047. The labeling is being updated due to a review of clinical trial data.

The data included in the updated label provide new information on SEROQUEL and hyperglycemia. The data presented are from three sources. Glucose data were examined from 1) two long-term trials investigating treatment with SEROQUEL and a mood stabilizer to maintain an effect in patients with bipolar disorder; 2) a 6-month trial in schizophrenic patients designed to specifically examine atypical therapy and glucose metabolism; and 3) the pooling of placebo-controlled trials where duration of SEROQUEL therapy was less than 12 weeks.

The 2 long-term trials of SEROQUEL are D1447C00126, entitled "A Multicenter, Randomized, Parallel-group, Double-blind, Phase III Comparison of the Efficacy and Safety of Quetiapine Fumarate (oral tablets 400mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Lithium or Valproate) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients" and Trial D1447C00127, entitled "A Multicenter, Randomized, Parellel-group, Double-blind, Phase III Comparison of the Efficacy and Safety of Quetiapine Fumarate (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Lithium or Divalproex) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients" . These trials will be submitted as part of a supplemental NDA application in July 2007.

The 6 month trial D1441C00125, which was previously submitted to the Agency, is entitled "A 24-Week, International, Multi-centre, Open-label, Flexible-dose, Randomised, Parallel-Group, Phase IV Study to Compare the Effect on Glucose Metabolism of Quetiapine, Olanzapine, and Risperidone in the Treatment of Patients with Schizophrenia".

Regulatory Affairs
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The data from the pooled placebo-controlled trials has been submitted to FDA previously in several different applications.

AstraZeneca is also requesting a teleconference approximately 5-7 days before the 30-day review expires.

Changes to the labeling appear in the following sections:

WARNINGS, Hyperglycemia and Diabetes Mellitus: A cross reference to the ADVERSE REACTIONS, Hyperglycemia sub-section has been added.

ADVERSE REACTIONS, Laboratory Changes, a new sub-section under the heading "Hyperglycemia" has been added.

The following files have been included in this submission:

1. SEROQUEL Labeling History-outstanding labeling supplements that may affect the review of this Special Supplement-Changes Being Effected (CBE) Supplement.

2. SEROQUEL Labeling Text-annotated and non-annotated versions of the Final Printed Labeling, which reflect changes noted in the CBE.

3. Structured Product Labeling-The final printed labeling in SPL format

4. Supporting documentation- Glucose Dysregulation in Patients treated with SEROQUEL (quetiapine)

This electronic submission has been scanned using Symantec AntiVirus, Version 10.1.5.5001 (Corporate Edition), with a virus definition file dated 20June07. No viruses were detected, and AstraZeneca certifies that the submission is virus-free.

This submission contains trade secrets and confidential commercial information exempt from public disclosure pursuant to exemption 4 of the Freedom of Information Act and FDA regulations, and the disclosure of which is prohibited by the Federal Food, Drug, and Cosmetic Act, the Trade Secrets Act, and other applicable law. Pursuant to FDA regulations, AstraZeneca is entitled to notice, an opportunity to object, and an opportunity to seek pre-release judicial review in the event that FDA determines that all or any part of this submission may be disclosed.

Please direct any questions or requests for additional information to me, or in my absence, to Gerald Limp, Director at (302) 886-8017.

Sincerely,

Kathryn Bradley, Associate Director
Regulatory Affairs
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