DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020639/S-051

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Pat Patterson
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Patterson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 26, 2010 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Seroquel (quetiapine fumarate) 25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg tablets.

We acknowledge receipt of your amendment dated March 10, 2011.

This "Prior Approval" supplemental new drug application provides for the following changes to labeling:

1) Addition of text regarding tardive dyskinesia syndrome may arise after discontinuation of treatment in Tardive Dyskinesia (section 5.7)
2) Addition of the incidence rates of discontinuation symptoms in Withdrawal (section 5.22)
3) Addition of text about decreases in hemoglobin to ≤ 13 g/dl males and ≤ 12 g/dl females in Adverse Reactions (section 6.2)
4) Addition of text in the highlights, drug interaction, and Medication Guide sections stating that false positive urine drug screens using immunoassays for methadone or tricyclic antidepressants have been reported in patients taking quetiapine.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter. The agreed-upon labeling is attached.

We note that the attached labeling includes language submitted under "Changes Being Effected" supplemental application submitted on January 14, 2011 (S-053) which is currently under review by the Division.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The Risk Evaluation and Mitigation Strategy (REMS) for Seroquel was originally approved on December 2, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of a revised Medication Guide to include information regarding interference with urine drug screens for methadone or tricyclic antidepressants in patients taking quetiapine.

The timetable for submission of assessments of the REMS will remain the same as that approved on December 2, 2009.

There are no changes to the REMS assessment plan described in our December 2, 2009 letter.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have questions, call Kimberly Updegraff, M.S., Senior Regulatory Project Manager, at (301)796-2201.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

THOMAS P LAUGHREN
05/17/2011