DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20639/S-061
NDA 22047/S-034

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Patricia 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 Applications (sNDA) dated and received July 15, 2013, 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, 400 mg tablets (NDA 20639/S-061) and Seroquel XR (quetiapine fumarate) Extended-Release 50 mg, 150 mg, 200 mg, 300 mg and 400 mg tablets (NDA 22047/S-034).

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to product labeling:

Seroquel (NDA 20639/S-061)

1. Administrative and editorial changes throughout labeling.
2. New subsection under Dosage and Administration section (2.1).
3. Add "pancreatitis" to the Post-Marketing Experience section (6.2)
4. Revisions to Pregnancy section (8.1)

Seroquel XR (NDA 22047/S-034)

1. Administrative and editorial changes throughout labeling.
2. Revisions to the Highlights section.
3. Addition of "rhabdomyolysis" to the Post-Marketing section (6.2).
4. Revisions to the Clinical Studies section (14).
5. Revisions to the Medication Guide.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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, and 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 that includes labeling changes 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).

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 any questions, contact Kimberly Updegraff, M.S., Regulatory Project Manager, at (301)796-2201.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:
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/

MITCHELL V Mathis
10/29/2013