DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

020639/S-060/S-063
022047/S-033/S-037

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
U.S. Agent for AstraZeneca UK Limited
Attention: Robert Griffin
Global Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Griffin:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received February 28, 2013 (NDAs 020639/S-060 & 022047/S-033), and August 21, 2014 (NDAs 020639/S-063 & 022047/S-037), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for (FDCA) for Seroquel (quetiapine fumarate) 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, 400 mg tablets (NDA 020639) and Seroquel XR (quetiapine fumarate) Extended-Release 50 mg, 150 mg, 200mg, 300 mg and 400 mg tablets (NDA 022047).

We acknowledge receipt of your amendment dated October 14, 2014, which constituted a complete response to our October 29, 2013, action letter.

These Prior Approval supplemental new drug applications provide for the following changes to the prescribing information for Seroquel and Seroquel XR:

- Revisions to the Leukopenia, Neutropenia and Agranulocytosis section under Warnings and Precautions.
- Addition of a new subsection entitled Anti-cholinergic (anti-muscarinic) Effects under Warnings and Precautions.
- Revisions to the Postmarketing Experience section under Adverse Reactions.
- Revisions to the Overdosage section.
- Revisions to the Patient Counseling Information section.
- Revisions to the Medication Guide.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 Prescribing Information, 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 include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Danbi Lee, Regulatory Project Manager, at danbi.lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Division Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Prescribing Information
Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TIFFANY R FARCHIONE
11/29/2018
On behalf of Mitch Mathis