DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020639/S-049/S-054

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 Applications (sNDA) dated and received January 15, 2010 (S-049) and March 22, 2011 (S-054), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Seroquel (quetiapine fumarate) Tablets.

- NDA 020639/S-049: Your March 25, 2011, submission constituted a complete response to our February 4, 2011 action letter. We acknowledge receipt of your April 1, 2011 submission containing amended labeling.

  This "Prior Approval" supplemental new drug application proposes revisions to include text regarding QT prolongation associated with quetiapine overdose in the Highlights section, sections 5.21 (Warnings and Precautions: Use in Patients with Concomitant Illness), 7 (Drug Interactions) and 10 (Overdosage). The supplement also contains modifications to sections 8.1 (Pregnancy), 8.3 (Nursing Mothers), Highlights - Use in Specific Populations and the Medication Guide as well as editorial revisions throughout labeling.

- NDA 020639/S-054: We acknowledge receipt of your amendment dated May 27, 2011 containing amended labeling.

  This "Changes Being Effected" supplemental new drug application provides for adding the term "hypothermia" to Section 6.3 Postmarketing Experience.

We have completed our review of these supplemental applications. They are 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, 201 (b) (4) The language submitted under this "Changes Being Effected" supplemental application is currently under review by the Division.

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).

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 a statement about breast feeding for consistency with the language in the pregnancy and nursing sections of labeling.

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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, call Kimberly Updegraff, Senior Regulatory Project Manager, at (301) 796-2201.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
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/

THOMAS P LAUGHREN
07/08/2011