DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022047/S-028

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT

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 July 19, 2011 and received on July 20, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Seroquel XR (quetiapine fumarate) Extended-Release Tablets 50 mg, 150 mg, 200 mg, 300 mg and 400 mg.

We acknowledge receipt of your amendment dated October 31, 2011 containing an updated Medication Guide.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 31, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be adequate.

This supplemental new drug application provides for revisions to the Medication Guide consisting of modifications aimed at increasing patient awareness of the risks associated with the use of Seroquel XR (quetiapine fumarate) Extended-Release Tablets, including mortality in elderly, hyperglycemia, hypercholesterolemia, and weight gain. The supplement also proposes to eliminate the requirement for the approved Seroquel XR (quetiapine fumarate) Extended-Release Tablets REMS.

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

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 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 (REMS) REQUIREMENT

The REMS for Seroquel XR (quetiapine fumarate) Extended-Release Tablets was originally approved on December 2, 2009, and the most recent REMS modification was approved on July 8, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Seroquel XR (quetiapine fumarate) Extended-Release Tablets.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Seroquel XR (quetiapine fumarate) Extended-Release Tablets outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Seroquel XR (quetiapine fumarate) Extended-Release Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling for Seroquel XR in accordance with 21 CFR 208.

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, 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:
Approved Medication Guide

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
11/09/2011