

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**020639Orig1s049**

**OTHER ACTION LETTERS**



NDA 20639/S-049 & 22047/S-023

**COMPLETE RESPONSE**

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, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Seroquel (quetiapine fumarate) Tablets (NDA 020639) and Seroquel XR (quetiapine fumarate) Extended-Release Tablets (NDA 022047).

We acknowledge receipt of your amendments dated February 17, 2010 and July 14, 2010, providing for additional information as requested by the Agency in communications dated February 11, 2010 and June 24, 2010.

We also acknowledge receipt of your amendment dated December 14, 2010 containing revised labeling based on our December 1, 2010 approval letter. You may incorporate applicable sections of the amendment by specific reference as part of your response to the deficiencies cited in this letter.

These "Changes Being Effected" labeling supplemental new drug applications propose 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), as well as editorial revisions throughout labeling.

We have completed the review of your applications, as amended, and have determined that we cannot approve these applications in their present form. We request that you submit draft labeling that incorporates the revisions outlined in the attached labeling for Seroquel (NDA 020639). We request similar changes be made to the labeling for Seroquel XR (NDA 022047).

In addition, submit updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

When responding to this letter, submit labeling that includes all previous revisions, as reflected in the most recently approved package insert. 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 include annotations with the supplement number for previously-approved labeling changes.

**OTHER**

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the supplemental application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants", May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

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

73 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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THOMAS P LAUGHREN  
02/04/2011