



NDA 20-639/S-031/S-039

AstraZeneca Pharmaceuticals LP
Attn: Gerald Limp, Director – Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Limp:

We acknowledge receipt of your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) tablets dated February 13, 2007 (S-031) and October 11, 2007 (S-039).

We additionally refer to e-mail communications from the Agency dated August 15, 2007 and September 19, 2007, requesting additional revisions to the labeling, and your e-mail dated September 24, 2007 accepting these changes with minor revisions. Your minor revisions were accepted by the Agency in our e-mail communication dated September 27, 2007.

These new drug applications, submitted under “Changes Being Effected” provide for the following revisions to labeling:

S-031

- This submission provides for changes in the Laboratory Changes under the section of ADVERSE REACTIONS and OVERDOSE sections. Additionally, cardiomyopathy and myocarditis have also been added to the ADVERSE REACTION section.

S-039

1. Revisions to the **PRECAUTIONS – Leukopenia, Neutropenia, and Agranulocytosis** section.
2. Revisions to the **PRECAUTIONS – Information for Patients** section.
3. Revisions to the **Laboratory Tests** section.
4. Revisions to the **Adverse Events – Laboratory Changes** section.
5. Revisions to the **Post-Marketing Experience** section.

We have completed our review of these applications, and they are approved, effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH

Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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 Sonny Saini, Pharm. D., Safety Regulatory Project Manager, at sonny.saini@fda.hhs.gov.

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Thomas Laughren
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