DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-047/S-013

AstraZeneca LP
Attention: Gregory Rullo, Director Regulatory Affairs - CMC
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Rullo:

Please refer to your supplemental new drug application dated and received April 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel® XR (quetiapine fumarate) Extended-Release Tablets, 50 mg, 200 mg, 300 mg, and 400mg.

We acknowledge receipt of your submissions dated April 24 and July 22, 2008.

This supplemental new drug application provides for a new 150 mg strength tablet.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling dated April 14, 2008, submitted in structure product labeling format and attached to this letter.

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, M.S., 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

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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