DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-047/S-002

AstraZeneca UK Limited
Attention: Gerald L. Limp, Regulatory Affairs Director
1800 Concord Pike P.O. Box 8355
Wilmington, DE 19803-2822

Dear Mr. Limp:

Please refer to your supplemental new drug application dated September 13, 2007, received September 13, 2007, 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 400 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change to the tablet intagliation from SR to XR.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1) in structured product labeling (SPL) format submitted on September 13, 2007.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure – word version of content of labeling submitted on September 13, 2007

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/s/

Jim Vidra

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