DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639/S-021

AstraZeneca LP
Attention: Gerald Limp
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Limp:

Please refer to your supplemental new drug application dated December 20, 2004, received December 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) Tablets.

This submission constituted a complete response to our December 10, 2004 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate packaging site to produce a new Seroquel Starter Physician's Sample Package for Seroquel 25 mg, 100 mg, and 200 mg tablets.

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

The final printed labeling (FPL) must be identical to the the submitted labeling (immediate container labels) submitted December 20, 2004.

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 Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

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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