DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639 / S-023

AztraZeneca Pharmaceuticals, LP
Attention: Kathryn Bradley
Associate Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19850-8355

Dear Ms. Bradley:

Please refer to your supplemental new drug application dated May 9, 2005, received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) tablets.

Please also refer to the Division's approvable letter of June 16, 2005.

This supplement provides labeling in response to the Division's supplement request letter of April 11, 2005 requesting that all manufacturers of atypical antipsychotic drug products add a Boxed Warning and a Bolded Warning section to labeling to advise that elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death.

We acknowledge receipt of your submissions of June 21, 2005 and July 11, 2005. Your submission of June 21, 2005 constituted a complete response to our June 16, 2005 approvable letter.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 21, 2005 (copy attached).

If you have any questions, call LCDR 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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