DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639 / S-030

AstraZeneca Pharmaceuticals, LP
Attention: Kathryn E. Bradley, Associate Director
US Regulatory Affairs
1800 Concord Pike, PO Box 8355
Wilmington, DE 19850-8355

Dear Ms Bradley:

Please refer to your supplemental new drug application dated and received February 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) Tablets.

This "Changes Being Effected" supplemental new drug application provides for carton and container packaging to support the initial recommended dosing for bipolar depression.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 7, 2007.

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

Under 21 CFR 208, you are responsible for ensuring that the Medication Guide is available for every patient who is dispensed Seroquel. The carton/container labels for Seroquel must include a prominent and conspicuous instruction to provide the Medication Guide to each patient dispensed the drug. The labels must also state how the Medication Guide is provided (e.g., affixed on the container, provided with the product, etc.).

These carton/container revisions must be implemented at your next printing, and they can be reported in your next annual report.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, email CAPT Steven D. Hardeman, Chief, Project Management Staff, at Steven.Hardeman@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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