DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639 S-025, S-037, S-038, S-040

AstraZeneca Pharmaceuticals LP
Attn: Gerald Limp
Director, Regulatory Affairs
1800 Concord Pike, P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Limp:

Please refer to your supplemental new drug application [sNDA] 20-639 S-037, referenced above, which was submitted and received on July 19, 2007 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) Tablets.

Please also refer to your amendments to the above referenced sNDA, submitted on October 24, 2007, October 29, 2007, November 15, 2007, November 16, 2007, and February 12, 2008.

In addition, please refer to your labeling supplements, NDA 20-639 S-025, S-038, and S-040. S-025 was submitted on November 14, 2005 and received on November 15, 2005. S-038 was submitted and received on July 30, 2007. S-040 was submitted and received on February 15, 2008, and amended on February 25, 2008.

NDA 20-639 S-037 provides for the use of Seroquel as maintenance treatment for bipolar I disorder, as adjunctive therapy to lithium or divalproex.

NDA 20-639 S-025 provides for changes in the labeling to describe the metabolite, N-desalkyl quetiapine. NDA 20-639 S-038 provides for changes in the labeling to add information about restless legs and anaphylaxis to the Adverse Events section of labeling and information on concomitant use with protease inhibitors to the Drug Interactions section of labeling. NDA 20-639 S-040 provides requested class labeling revisions pertaining to dystonia.

We have completed our review of your submissions as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling, unless we notify you otherwise.

Content of Labeling: Structured Product Labeling [SPL]. the final printed labeling (FPL) must be identical to the enclosed labeling [package insert], and must be formatted in accordance with the requirements of 21 CFR 201.66.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured Product Labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html , that is identical to the enclosed agreed-upon labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA labeling under NDA 20-639 S-037".

Pediatric Research Equity Act (PREA) Requirements: Phase 4 Commitments.
Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 9 years because:

A) necessary studies are impossible or highly impracticable. This is because bipolar disorder cannot be reliably diagnosed in this age group, and therefore appropriate studies cannot be developed and carried out.

We are deferring submission of your pediatric studies for ages 10 to 17 years because:

B) pediatric studies should be delayed until additional safety or effectiveness data have been collected. We are aware that submission of pediatric studies under your existing Written Request is imminent, and these studies, once reviewed, may be sufficient to address the PREA requirement for this indication.

The deferred studies should be submitted by ***June 1, 2015.***

There are no other Phase 4 commitments or Phase 4 requirements for this submission.

"Dear Healthcare Professional" Letters.
If you issue a letter communicating important information about this product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA, with a copy to the following address:

MEDWATCH, HFD-410
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Introductory Promotional Materials.
In addition, submit three copies of the introductory promotional materials that you propose to use for this indication. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Reporting Requirements. 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, please call Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-796-1040.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling.

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
5/13/2008 10:49:19 AM