DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639 / S-026

AstraZeneca Pharmaceuticals LP
Attention: Gerald L. Limp
Regulatory Affairs Director
PO Box 8355
Wilmington, DE 19803-8355

Dear Mr. Limp:

Please refer to your supplemental new drug application dated December 30, 2005, received December 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel® (quetiapine) Tablets.

We acknowledge receipt of your submissions dated January 17, 2006, January 26, 2006, March 9, 2006, March 10, 2006, April 4, 2006, April 27, 2006, June 19, 2006, June 26, 2006, August 3, 2006, and September 25, 2006, and your secure email transmission dated October 18, 2006.

This supplemental new drug application provides for the use of Seroquel® in the treatment of major depressive episodes associated with bipolar disorder.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text [package insert].

The final printed labeling (FPL) must be identical to the enclosed agreed-upon labeling. These revisions are terms of the supplemental NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved Supplemental NDA 20-639/S-026.**" Approval of this submission by FDA is not required before the labeling is used.

Pediatric Rule: Partial Waiver, Partial Deferral
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for this application, for children aged 0-9 years [the condition is difficult to diagnose and treat in this age group]. We are deferring the submission of your

pediatric studies for ages 10 to 17 years until October 30, 2011. Your deferred pediatric study required under section 2 of the Pediatric Research Equity Act (PREA) is considered a required postmarketing study commitment, and is reiterated below:

1. Deferred pediatric study under PREA for the treatment of major depressive episodes associated with bipolar disorder in pediatric patients ages 10 to 17.
Final Report Submission: On or before October 30, 2011.

For the above Phase 4 Commitment, submit the clinical protocol(s) to your IND for this indication. Submit all study final reports to the NDA. All submissions, including supplemental New Drug Applications, relating to the Phase 4 Commitment must be prominently labeled **"Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence".**

The status of this postmarketing study shall be reported annually, according to 21 CFR 314.81, in your annual report to the NDA. The status summary should include expected protocol submission, study completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, the number of patients entered into each study.

Introductory Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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(s) 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

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 contact Doris J. Bates, Ph.D., Regulatory Project Manager, at (301).796.2260, or contact her via secure electronic mail at doris.bates@fda.hhs.gov.

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

Attachment: Final Agreed-Upon Labeling [Package Insert]

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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