CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022047Orig1s000

Trade Name:	Seroquel XR 50 mg, 200 mg, 300 mg, and 400 mg Extended-Release Tablets
Generic Name:	quetiapine fumarate
Sponsor:	AstraZeneca Pharmaceuticals LP
Approval Date:	May 17, 2007
Indications:	Treatment of schizophrenia

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-047

AstraZeneca Pharmaceuticals LP
Attention: Gerald Limp
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19850-8355

Dear Mr. Limp:

Please refer to your new drug application (NDA) dated July 17, 2006, received July 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel XR (quetiapine fumarate) 50 mg, 200 mg, 300 mg, and 400 mg Extended-Release Tablets.

We acknowledge receipt of your submissions dated:

August 10, 2006	August 30, 2006	September 19, 2006	October 3, 2006
October 17, 2006	October 25, 2006	November 16, 2006	November 30, 2006
January 8, 2007	January 29, 2007	March 7, 2007	March 20, 2007
April 5, 2007	April 12, 2007	April 16, 2007	April 30, 2007
May 3, 2007			

This new drug application provides for the use of Seroquel XR (quetiapine fumarate) Extended-Release Tablets for the treatment of schizophrenia.

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

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit 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 in content to the enclosed 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 22-047"

50 Mg Tablet Strength

We recognize that, although we have approved the 50 mg dosage strength, you do not plan to market the product at this time and it is not included in the attached labeling.

Dissolution Method and Specification

The following dissolution method and specification are acceptable for Seroquel XR (quetiapine fumarate) Extended-Release Tablets 50 mg, 200 mg, 300 mg, and 400 mg strengths.

Apparatus	USP Apparatus I (Basket)
Speed	200 RPM
Media	900 mL 0.05M Sodium Citrate and 0.09N Sodium hydroxide (pH 4.8). At 5 hours, pH adjusted to 6.6 with 100 mL medium of 0.05M Sodium Phosphate and 0.46N Sodium Hydroxide
Specification:	Not more than (NMT) (b) (4) at 1 hour (b) (4) at 6 hours (b) (4) at 12 hours Not less than (NLT) (b) (4) at 20 hours.

Expiry

Based on your submitted stability data, we are granting a 36 month expiry for all commercial packages of Seroquel XR (quetiapine fumarate) Extended-Release Tablets when stored at 25^{o}C.

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 0-12 years. We are deferring the submission of pediatric studies for ages 13 to 17 years until February 11, 2010. 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.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated **"Required Pediatric Study Commitments"**.

Phase 4 Postmarketing Commitments

1. Deferred Pediatric Studies Under PREA

   You are required to assess the safety and effectiveness of quetiapine fumarate (as either the immediate release or the extended release formulation) as a treatment for schizophrenia in pediatric patients ages 13 to 17.

   Final Report Submission: On or before February 11, 2010.

2. Tablet Intagliation

   You have agreed to modify the tablet intagliation to XR plus dosage strength which addresses the preference of the Agency that the intagliation more closely resemble the proprietary name modifier. We additionally note your commitment to submit this change in the form of a "Changes Being Effected in 30 days" supplemental application to your NDA.

   Final Report Submission: On or before October 30, 2007.

3. Studies to Investigate Dose-Dumping in the Presence of Alcohol

   You have agreed to conduct studies to investigate dose-dumping in the presence of alcohol. You will perform dissolution studies for all Seroquel XR strengths using the accepted dissolution conditions with the addition of 0%, 5%, 20%, and 40% of ethanol to the dissolution media.

   Final Report Submission: On or before August 31, 2007.

For the above Postmarketing Commitments, 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.

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 the Division of Psychiatry Products 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

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 Kimberly Updegraff, M.S., R.Ph., Regulatory Project Manager, at (301) 796-2201.

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

Enclosure

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
5/17/2007 03:20:17 PM