

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 22-047 S-006, S-007, and S-008

Trade Name: Seroquel XR

Generic or Proper Name: Quetiapine Fumarate

Sponsor: AstraZeneca

Approval Date: October 19, 2008

Indication: SEROQUEL XR is indicated for the acute and maintenance treatment of schizophrenia. SEROQUEL XR is indicated for acute treatment of depressive episodes associated with bipolar disorder; acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy and as an adjunct to lithium or divalproex therapy; maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex.

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NDA 22-047 S-006, S-007, and S-008

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APPLICATION NUMBER:

NDA 22-047 S-006, S-007, and S-008

APPROVAL LETTER



NDA 22-047 S-006, S-007, S-008

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 applications [sNDAs] 22-047 S-006, S-007, and S-008, referenced above, which were submitted and received on December 19, 2007 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel XR (quetiapine fumarate) Extended-Release Tablets.

Please also refer to your amendments to the above referenced sNDAs, submitted as shown:

S-006	S-007	S-008
January 10, 2008	January 14, 2008	January 14, 2008
January 28, 2008	January 28, 2008	January 28, 2008
February 28, 2008	February 28, 2008	February 28, 2008
March 27, 2008	March 28, 2008	March 28, 2008
June 5, 2008	June 5, 2008	June 4, 2008
August 28, 2008	August 28, 2008	August 28, 2008
September 12, 2008	September 12, 2008	September 12, 2008
September 25, 2008	September 25, 2008	September 25, 2008

NDA 22-047 S-006 provides for the use of Seroquel XR as monotherapy in the treatment of bipolar depression. NDA 22-047 S-007 provides for the use of Seroquel XR as monotherapy in the treatment of bipolar mania; NDA 22-047 S-008 provides for the use of Seroquel XR as adjunctive therapy in the treatment of bipolar mania. In addition, all three supplements provide for the use of the previously approved [but not previously marketed] 50 mg tablet for initiation of dose titration at a lower starting dose.

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 [package insert, plus container labeling for the 50 mg tablet strength.]

Content of Labeling: Structured Product Labeling [SPL]. The final printed labeling (FPL) must be identical to the enclosed agreed-upon 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 [package insert]. 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 all three of the adult indications approved with this letter, 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) Approval of this product for adults in the indications of interest has just occurred with the issuance of this letter.

The indications for which studies are deferred are the following:

S-006:

1. Deferred pediatric study under PREA for the use of Seroquel XR as monotherapy in the treatment of bipolar depression.
Final Report Submission: June 1, 2015.

S-007:

1. Deferred pediatric study under PREA for the use of Seroquel XR as monotherapy in the treatment of bipolar mania.
Final Report Submission: June 1, 2015.

S-008:

1. Deferred pediatric study under PREA for the use of Seroquel XR as adjunctive therapy in the treatment of bipolar mania.
Final Report Submission: June 1, 2015.

There are no other Phase 4 commitments or Phase 4 requirements for these submissions.

"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 these indications. 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, market container/carton labels for 50 mg strength.

**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
10/8/2008 12:25:18 PM