

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-172s000

APPROVAL LETTER



NDA 22-172

NDA APPROVAL

AstraZeneca
Attention: Gerald Limp
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Limp:

Please refer to your new drug application (NDA) dated and received January 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel XR (quetiapine fumarate) 50mg, 200mg, 300mg, and 400mg Extended-Release Tablets.

We acknowledge receipt of your submissions dated:

January 22, 2007
August 9, 2007

April 26, 2007
September 26, 2007

July 11, 2007

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

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

We are waiving the requirements of 21 CFR 201.157(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.

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.

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(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical 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 22-172."

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.

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 children aged 0 to 17 years for this application since it would likely not be feasible to conduct the study of the required design in this age group.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 22-047 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

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If you have any questions, call Kimberly Updegraff, R.Ph, M.S., 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