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*APPLICATION NUMBER:*

**022047Orig1s000**

**PHARMACOLOGY REVIEW(S)**

## PHARMACOLOGY/TOXICOLOGY MEMORANDUM

NDA 22-047

Letter Date: July 17, 2006

Seroquel SR (Sustained Release) Tablets

Sponsor:

AstraZeneca Pharmaceuticals LP

Gerald Limp

Director Regulatory Affairs

Telephone: (302) 886-8017

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Drug: SEROQUEL® SR (quetiapine fumarate) Sustained Release Tablets

Indication: Treatment of schizophrenia

Reviewer: Sonia Tabacova, Ph.D.

Date: March 23, 2007

This New Drug Application for SEROQUEL® SR (quetiapine fumarate sustained release tablets) was submitted electronically on July 17, 2006 (Internal Filing Meeting: August 31, 2006).

SEROQUEL® (immediate release tablets) was previously approved for the treatment of schizophrenia on 26 September 1997 (NDA 20-639). AstraZeneca developed sustained-release (SR) tablets for the treatment of schizophrenia that will allow administration of quetiapine once daily in the dose range of 400 to 800 mg/day.

Note: This NDA does not have Module 4 "Preclinical Pharmacology and Toxicology" according to a previous agreement with the Division. The format and content of this NDA "are consistent with agreements made during the 20 June 2002 pre-NDA meeting and all subsequent correspondence" As explained in the sponsor's letter, "During pre-NDA discussions, the Division agreed that the preclinical data on quetiapine in the approved NDA 20-639 were supportive of SEROQUEL SR tablets and that further preclinical animal studies of the SR formulation were unnecessary; therefore, Module 4 has not been provided."

At the IND 45,456 SEROQUEL SR pre-NDA Meeting of the Division with AstraZeneca (June 20, 2002) "FDA agreed that no preclinical animal data is needed, provided the to-be-marketed formulations of SEROQUEL SR have AUC's that are similar to the current marketed IR formulation. FDA referenced the illustration in the briefing document of data from Trial 97, where it appeared that there were similar exposures between the new SR formulation and the marketed SEROQUEL immediate-release (IR) formulation." (IND 45,456 SN 82, Meeting Minutes of June 20, 2002)

Since preclinical pharmacology and toxicology data were not submitted, no pharm/tox review of the current application is performed. However, as the labeling for this application is made according to a new format, we reviewed the submitted draft labeling for SEROQUEL SR tablets to make sure that all preclinical information in the existing labeling for the approved Seroquel® IR (Immediate Release) Tablets is accurately reflected in the proposed labeling for Seroquel® SR.

Conclusion: This NDA does not have Module 4 "Preclinical Pharmacology and Toxicology" according to a previous agreement with the Division. The submitted draft labeling for SEROQUEL SR tablets is fully consistent with the existing labeling for the approved Seroquel® IR (Immediate Release) Tablets with respect to the preclinical pharm/tox data.

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/s/

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Sonia Tabacova  
4/16/2007 10:48:13 AM  
PHARMACOLOGIST/TOXICOLOGIST

Aisar Atrakchi  
4/16/2007 11:05:00 AM  
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