

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

020639Orig1s049

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

Updegraff, Kimberly

From: Updegraff, Kimberly
Sent: Thursday, June 24, 2010 10:47 AM
To: Patterson, Pat
Cc: Updegraff, Kimberly
Subject: Information Request: NDA 20-639/SLR-049; NDA22-047/SLR-023

Dear Pat,

Please refer to your submission dated 01/15/2010 for NDAs 20639 (Seroquel) and 22047 (Seroquel XR), which contains a CBE labeling supplement with QT prolongation data. For the QT data in placebo-controlled clinical trials, please provide data from fixed dose studies to look for a dose-response relationship. Also, please provide your result tables "by dose" (in both Microsoft Word and pdf format) for: 1) mean QTc change from baseline; 2) shift changes to potentially clinically important QTcF values ≥ 500 ms; 3) ≥ 60 ms increase shift.

Best regards,

Kim

Kimberly Updegraff, MS, RAC
Senior Regulatory Project Manager
Division of Psychiatry Products
Center for Drug Evaluation and Research, FDA
Office of Drug Evaluation
Phone: (301)796-2201

6/24/2010

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22047	SUPPL-23	ASTRAZENECA PHARMACEUTICA LS LP	SEROQUEL XR
NDA-20639	SUPPL-49	ASTRAZENECA LP	SEROQUEL(QUETIAPINE FUMARATE)25/100/200M

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/s/

KIMBERLY S UPDEGRAFF
06/24/2010

Updegraff, Kimberly

From: Updegraff, Kimberly
Sent: Thursday, February 11, 2010 10:04 AM
To: Patterson, Pat
Cc: Updegraff, Kimberly
Subject: NDA 20639 (Seroquel) and NDA 22047 (Seroquel XR) - CBE

Dear Pat,

Please refer to your Changes Being Effectuated supplements dated 01/15/2010 for NDA 20639 (Seroquel) and NDA 22047 (Seroquel XR). We note you have conducted a review of the AZ Clinical Trial Safety Database, Global Safety Database, 34 post-marketing cases of QT prolongation and overdose and medical literature search which led to the proposed labeling changes in this supplement. However, data from these sources was not provided for us to review. We appreciate if you can submit to the above mentioned NDAs the summary of the data and, in particular, the following:

1. Line listing of Postmarketing cases with reported 'verbatim term' and 'coded term'.
2. Medwatch reports for the 34 Post-marketing cases of QT prolongation and overdose.
3. A summary of your findings from medical literature search on this issue including a list of references and copies of any relevant articles.

We would like you to respond to this request by COB on Wednesday, 02/17/2010.

Best regards,

Kim

Kimberly Updegraff, RPh, MS, RAC
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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20639	SUPPL-49	ASTRAZENECA LP	SEROQUEL(QUETIAPINE FUMARATE)25/100/200M

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/s/

KIMBERLY S UPDEGRAFF
03/29/2010