NDA 020639/S-068

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
U.S. Agent for: AstraZeneca UK Limited
Attention: Emery Gigger, Regulatory Affairs Director
1800 Concord Pike
Wilmington, DE 19803

Dear Mr. Gigger:

Please refer to your Supplemental New Drug Application (sNDA) dated October 3, 2019, received October 15, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SEROQUEL (quetiapine fumarate) Tablets, 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, and 400 mg.

This Prior Approval supplemental new drug application provides for the following labeling changes per the Agency's recommendation received on 10/30/2018:

- Revise the established name to "Quetiapine tablets" and "Quetiapine extended-release tablets" respectively on the container labels and the PI from the currently used "Quetiapine fumarate tablets" and "Quetiapine fumarate extended-release tablets" to correspond to the titles of the USP monographs for these drug products.

- Revise the "Dosage Forms and Strengths" and "Description" sections of the PI and the container carton labels for Seroquel® and Seroquel® XR to add an equivalency statement to indicate the amount of active ingredient (quetiapine fumarate) relative to the labeled amount of the active moiety (quetiapine)

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending

"Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your February 20, 2020, submission containing final printed carton and container labels.

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, call Kimberly Hudgens, Regulatory Business Process Manager, at (240) 402 - 4884.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Container Labeling

David Lewis

Digitally signed by David Lewis
Date: 3/27/2020 01:46:47PM
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