REMS

NDA 22-047
SEROQUEL® XR (quetiapine fumarate) Extended-Release Tablets
Atypical Antipsychotic
AstraZeneca Pharmaceuticals LP
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of SEROQUEL XR® (quetiapine fumarate) Extended-Release Tablets.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each SEROQUEL XR prescription. In accordance with 21 CFR 208.24(b), AstraZeneca Pharmaceuticals LP (AstraZeneca) will make the Medication Guide available for distribution to patients by providing the means to permit authorized dispensers to produce the Medication Guides in sufficient numbers to meet the dispenser obligations under 21 CFR 208.24(e) to provide a Medication Guide to each patient receiving a prescription for SEROQUEL XR.

In accordance with 21 CFR 208.24(d) a statement will be included on the container label for SEROQUEL XR to alert pharmacists to dispense the Medication Guide with each prescription of the product. The following statement will be included on the container label, "Medication Guide must be dispensed to patients."

B. Timetable for Submission of Assessments

AstraZeneca will submit REMS Assessments to FDA 18 months, 3 years and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. AstraZeneca will submit each assessment so it will be received by the FDA on or before the due date.