

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-411

REMS

APPENDIX A: PROPOSED REMS

NDA 022411 – OLEPTRO™ (trazodone hydrochloride) Extended Release Tablets

Serotonin 2A Antagonist Reuptake Inhibitor

Labopharm Europe Limited

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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 OLEPTRO™ (trazodone hydrochloride) Extended Release Tablets.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each OLEPTRO™ (trazodone hydrochloride) prescription in accordance with 21 CFR 208.24. Additionally, carton labeling and container labels will bear the following statement:

“Dispense accompanying Medication Guide to each patient.”

The Medication Guides will be supplied to pharmacists as tear-pads of 18 Medication Guides, plus a cover sheet which provides instructions to the dispensers.

In order for a Medication Guide be distributed to each patient, each shipment of product to pharmacies will include sufficient printed Medication Guides for the maximum number of prescriptions possible from that shipment (based on an average prescription for 30 days).

B. Timetable for Submission of Assessments

Labopharm Europe Limited will submit REMS Assessments to the FDA by 18 months, by 3 years, and in the 7th year from the date of 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. Labopharm Europe Limited

will submit each assessment so that it will be received by the FDA on or before the due date.