NDA 21-520, SYMBYAX (olanzapine and fluoxetine hydrochloride) Capsule for Oral Use

Contact: Roland Usher
Eli Lilly and Company
Office: 317.277.4327

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. Goals(s)

The goal of the REMS is to inform patients of the serious risks associated with the use of Symbyax (olanzapine and fluoxetine hydrochloride) Capsule for Oral Use, including the risks of suicidality, hyperglycemia, hyperlipidemia, and weight gain.

II. REMS Elements

A. Medication Guide

The Medication Guide will be dispensed with each Symbyax prescription in accordance with 21 CFR 208.24.

B. Communication Plan

This REMS for Symbyax does not include a Communication Plan.

C. Elements to Assure Safe Use

This REMS for Symbyax does not include elements to assure safe use.

D. Implementation System

Because this REMS for Symbyax does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The Timetable for Assessments is as follows:

- First FDAAA assessment: September 2010 (18 months from approval)
- Second FDAAA assessment: March 2012 (3 years from approval)
- Third FDAAA assessment: March 2016 (7 years from approval)

Eli Lilly and Company will submit the assessments within 60 days of the close of the intervals as noted above.