NDA 20-592, ZYPREXA (olanzapine) Tablet for Oral Use
NDA 21-086, ZYPREXA ZYDIS (olanzapine) Tablet, Orally Disintegrating for Oral Use

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 Zyprexa (olanzapine) Tablet for Oral Use and Tablet, Orally Disintegrating for Oral Use, including the risks of hyperglycemia, hyperlipidemia, and weight gain.

II. REMS Elements

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

B. Communication Plan
This REMS for Zyprexa does not include a Communication Plan.

C. Elements to Assure Safe Use
This REMS for Zyprexa does not include elements to assure safe use.

D. Implementation System
Because this REMS for Zyprexa 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:

- The first assessment is due 18 months from the original approval date of the REMS (September 19, 2010).
  The second assessment is due 3 years from the original approval date of the REMS (March 19, 2012).
- The third assessment is due 7 years from the original approval date of the REMS (March 19, 2016).

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. Eli Lilly and Company will submit each assessment so it will be received by the FDA on or before the due dates listed above.