

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**022567Orig1s000**

**REMS**

NDA 22-567 vilazodone HCl Tablets

**Viibryd™**

*(vilazodone hydrochloride)*

**Class of Product:** Antidepressant

PGxHealth, LLC

5 Science Park

New Haven, CT 06511

**Contact Information: PGxHealth, LLC (1-877-878-7200)**

**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 vilazodone HCl Tablets.

## **II. REMS ELEMENTS:**

### **A. Medication Guide**

PGxHealth, LLC, will ensure that a currently approved Medication Guide will be dispensed with each vilazodone prescription in accordance with 21 CFR 208.24.

### **B. Timetable for Submission of Assessments**

PGxHealth, LLC, will submit REMS Assessments to FDA at 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. PGxHealth, LLC will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/  
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ELLIS F UNGER  
01/21/2011