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/

ELLIS F UNGER
01/21/2011