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***APPLICATION NUMBER:***

# 022567Orig1s000

# CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

# Clinical Pharmacology Review Amendment

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| **NDA** | 22567 |
| **Submission Dates:** | March 22, 2010, August 31, 2010 |
| **Brand Name:** | Viibryd |
| **Generic Name:** | Vilazodone |
| **Strength and Formulation:** | 10, 20, and 40 mg IR tablets |
| **Sponsor:** | PGxHealth, LLC |
| **Indication:** | Major Depressive Disorder (MDD) |
| **Submission Type:** | Original NDA (NME) |
| **CP Reviewer Team:** | Bei Yu, Ph.D., Huixia Zhang, Ph.D., Jee Eun Lee, Ph.D., Joga Gobburu, Ph.D. Atul Bhattaram, Ph.D. Yaning Wang, Ph.D., Issam Zineh, PharmD, MPH, FCCP., Li Zhang, Ph.D. |

(b) (4)

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/s/

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BEI YU
12/10/2010

JOGARAO V GOBBURU
12/10/2010
The original full OCP review was signed-off on 8Dec2010. This review amends a typo in the labeling recommendations.

# ONDQA BIOPHARMACEUTICS REVIEW

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| **NDA#**: | 22-567 (N-000) |
| **Submission Date:** | 03/22/10, 10/29/10, and 11/30/10 |
| **Brand Name:** | Pending |
| **Generic Name**: | Vilazodone HCl |
| **Formulation:** | Oral immediate-release (IR) tablets |
| **Strength**: | 10, 20, and 40 mg |
| **Sponsor**: | PGx Health |
| **Type of submission:** | Original |
| **Reviewer**: | Tien-Mien Chen, Ph.D. |


**SUMMARY**

Vilazodone HCl, is reportedly a dual-acting potent and selective serotonin reuptake inhibitor and 5-$HT_{1A}$ receptor partial agonist. Vilazodone is a new chemical entity (NME) which was developed (up to 20 mg strength) by Merck and GSK as the first in a new class of antidepressants – the dual-acting serotonergic antidepressants.

On 03/22/10, PGx Health submitted NDA 22-567 (N-000) for Vilazodone HCl tablets. Vilazodone HCl is formulated as 10 mg, 20 mg, and 40 mg, film-coated IR tablets and is indicated for the treatment of major depressive disorder (MDD). The to-be-marketed (TBM) tablets are manufactured using a (b) (4) All 10, 20 and 40 mg tablets are (b) (4) and dose proportional and have been used in the Phase 3 clinical trials and several Phase 1 studies. Therefore, there is no biowaiver issue.

Six batches of Vilazodone HCl Tablets (three for each of 10 mg and 40 mg tablet strengths) are included in the primary registration stability study. These batches were manufactured using the intended commercial formulation, at the intended commercial facility using the intended commercial process. All batches were manufactured at (b) (4) scale, which is (b) (4) of the intended commercial scale (b) (4)). Each batch was packaged in container closures intended for commercial products. The 20 mg strength is bracketed and not included in the stability studies.

The dissolution data on the 10 and 40 mg TBM tablet strengths were submitted, however, the dissolution data on the 20 mg TBM tablet strength could not be located in this submission. On 10/15/10, an information request was sent to the sponsor and the sponsor responded on 10/29/10 and 11/30/10. The dissolution development report, dissolution methodology and data/profile for all three strengths, and the proposed dissolution specifications are, therefore, reviewed here.

The following dissolution method and the specifications are proposed as shown below.

**USP Apparatus:** **2 (Paddle) x 60 rpm**
**Medium:** **0.1% Acetic Acid (pH 3.1), 1000 mL at 37ºC**
**Specifications:** **Q=** (b) (4) **at 30 min**

The results of dissolution testing show that all three strengths meet the proposed dissolution specifications.

**RECOMMENDATION**

From the Biopharmaceutics perspective, the proposed dissolution methodology and specifications are acceptable. No further comments need to be sent to the sponsor.

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