# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 022567Orig1s000

# PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services**

**Public Health Service**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Surveillance and Epidemiology**

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| Date: | November 15, 2010 |
| Application Type/Number: | NDA 022567 |
| Through: | Kristina A. Toliver, PharmD, Team Leader<br>Denise P. Toyer, PharmD, Deputy Director<br>Carol A. Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Loretta Holmes, BSN, PharmD, Safety Evaluator<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name: | Viibryd (Vilazodone Hydrochloride) Tablets<br>10 mg, 20 mg, and 40 mg |
| Applicant: | PGxHealth, LLC |
| OSE RCM #: | 2010-1849 |

***** This document contains proprietary and confidential information that should not be released to the public.*****

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## EXECUTIVE SUMMARY

This review summarizes DMEPA's proprietary name risk assessment of Viibryd for Vilazodone Hydrochloride Tablets, 10 mg, 20 mg, and 40 mg. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Viibryd, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA. The Applicant will be notified via letter of these findings.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 1 BACKGROUND

### 1.1 INTRODUCTION

This review responds to an August 23, 2010 request from PGxHealth, LLC for an assessment of the proposed proprietary name, Viibryd, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an independent name assessment completed by (b) (4)

Additionally, the container labels, carton and insert labeling are being evaluated for their potential contribution to medication errors under separate cover (OSE Review 2010-826).

### 1.2 REGULATORY HISTORY

The Applicant initially submitted the proposed name, (b) (4) for our evaluation. DMEPA found the name unacceptable (see OSE Review 2010-967, dated August 2, 2010) (b) (4)

Thus, the Applicant has submitted the proposed name, Viibryd, for our evaluation.

### 1.3 PRODUCT INFORMATION

Viibryd is the proposed proprietary name for Vilazodone Tablets. Viibryd is a dual-acting selective serotonin reuptake inhibitor and 5-$HT_{1A}$ receptor partial agonist, indicated for the treatment of major depressive disorder. The recommended dosage is 40 mg once daily. Viibryd should be titrated, starting with an initial dose of 10 mg once daily for seven days followed by 20 mg once daily for an additional seven days. Viibryd will be supplied in 10 mg, 20 mg, and 40 mg strengths. The following packaging configurations will be available: 30-count, 90-count, 500-count, 10 x 10 count blister cards, and a 30-count titration pack. Viibryd should be stored at room temperature.

## 2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Viibryd.

## 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'V' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

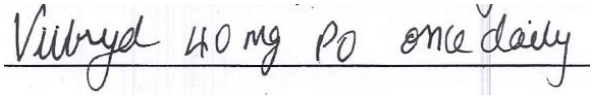
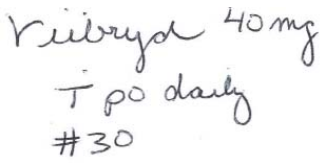
To identify drug names that may look similar to Viibryd, the DMEPA Safety Evaluators also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, lower case 'b' and 'd'), downstrokes (one, lower case 'y'), cross strokes (none), and dotted letters (two, lower case 'i' and 'i'). Additionally, several letters in Viibryd may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA Safety Evaluators also considers these alternate appearances when identifying drug names that may look similar to Viibryd.

When searching to identify potential names that may sound similar to Viibryd, the DMEPA Safety Evaluators search for names with similar number of syllables (two), stresses (VII-bryd or vii-BRYD), and placement of vowel and consonant sounds. Additionally, the DMEPA Safety Evaluators consider that pronunciation of parts of the name can vary (see Appendix B). The Applicant's intended pronunciation of the name is "VYE-brid". However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

**Figure 1. Viibryd Prescription Studies (conducted on September 2, 2010)**

| HANDWRITTEN REQUISITION MEDICATION ORDER | VERBAL PRESCRIPTION |
|---|---|
| Inpatient Medication Order:<br>  | "Viibryd 40 mg po once daily" |
| Outpatient Prescription:<br>  | |

[1] Institute for Safe Medication Practices. Confused Drug Name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

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