CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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<u>STATISTICAL REVIEW(S)</u>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION
CLINICAL STUDIES

NDA/Serial Number:	22-567 N000
Drug Name:	Vilazodone
Indication:	Major depressive disorder
Applicant:	PGxHealth
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Review Priority:	Standard
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Keywords: Clinical studies; NDA review

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1. EXECUTIVE SUMMARY

1.1 Conclusions and Recommendations

Vilazodone at a 40 mg/day was positive in the acute treatment of major depressive disorder, as measured by the change from baseline to week 8 in the Montgomery-Asberg Depression Rating Scale (MADRS) total score, based on two pivotal studies.

1.2 Brief Overview of Clinical Studies

This submission contains two pivotal, phase III studies to support the efficacy and safety of vilazodone in the acute treatment of major depressive disorder (MDD). Both studies were randomized, double-blind, placebo-controlled, parallel-group, multicenter, U.S. studies. Both studies investigated the efficacy and safety of vilazodone at a target dose of 40 mg/day. Patients went through a titration period to the target dose. The primary efficacy measure was the change from baseline to week 8 in the MADRS total score.

This NDA also contains five other studies that were either negative or failed and are not subject to this review.

1.3 Statistical Issues and Findings

Both pivotal studies were positive based on the primary efficacy variable pre-specified. None of the secondary efficacy measures were specified as key secondary efficacy measures or agreed upon a priori

(b) (4)

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The long-term efficacy of vilazodone has not been adequately assessed. The current data are based on a one year open-label study (Study CLDA-07-DP-04). Because this was an open-label and there was no control group, the efficacy evaluation is limited and is subject to biases. (b) (4)

2. INTRODUCTION

2.1 Overview

This review provides a statistical evaluation of the efficacy of vilazodone as an acute treatment of major depressive disorder (MDD).

As defined in the DSM-IV-TR, major depressive disorder (MDD) is a mental illness characterized by one or more major depressive episodes. A major depressive episode implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning. MDD includes at least 5 of the following 9 symptoms: depressed mood, loss of interest in usual activities,

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