CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022567Orig1s000

MEDICAL REVIEW(S)



CLINICAL REVIEW

Application Type NDA

Application Number(s) 022567

Related IND 054613

Priority or Standard Standard

Submit Date(s) March 22, 2010

Received Date(s) March 22, 2010

PDUFA Goal Date January 22, 2011

Division / Office DPP/ODE1

Reviewer Name(s) Cheri Lindberg, MD

Review Completion Date January 19, 2011

Established Name Vilazodone HCl

(Proposed) Trade Name Viibryd

Therapeutic Class Antidepressant

Applicant PGxHealth, LLC

Formulation(s) 10, 20, 40 mg tablet

Dosing Regimen Once daily - oral

Indication(s) Major Depressive Disorder

Intended Population(s) Adult



Template Version: March 6, 2009



Table of Contents

2 Risk Benefit Assessment	5
NTRODUCTION AND REGULATORY BACKGROUND	7
Tables of Currently Available Treatments for Proposed Indications	8 8 9
ETHICS AND GOOD CLINICAL PRACTICES	. 11
2 Compliance with Good Clinical Practices	. 11
DISCIPLINESDISCIPLINES	. 12
Clinical Microbiology Preclinical Pharmacology/Toxicology Clinical Pharmacology 4.4.1 Mechanism of Action 4.4.2 Pharmacodynamics 4.4.3 Pharmacokinetics	. 13 . 13 . 13 . 13 . 14
2 Review Strategy	. 20
REVIEW OF EFFICACY	. 39
6.1.1 Methods	. 39 . 43 . 45 . 48 . 49
	Risk Benefit Assessment. Recommendations for Postmarket Risk Evaluation and Mitigation Strategies INTRODUCTION AND REGULATORY BACKGROUND



7	REVIE	W OF SAFETY	. 64
	Safety S	ummary	. 64
	7.1 Me	ethods	
	7.1.1		
		Categorization of Adverse Events	. 66
	7.1.3	J I	
		Incidence	
		equacy of Safety Assessments	
	7.2.1	1 11 1	
	700	Target Populations	
	7.2.2	Explorations for Dose Response	
	7.2.3	Special Animal and/or In Vitro Testing	
	7.2.4	Routine Clinical Testing	
	7.2.5 7.2.6	Metabolic, Clearance, and Interaction Workup	
	_	Evaluation for Potential Adverse Events for Similar Drugs in Drug Class.	
	7.3 IVIZ	ijor Safety Results Deaths	
	7.3.1	Nonfatal Serious Adverse Events	
	7.3.2		
		Supportive Safety Results	
	7.4.1	Common Adverse Events	
	7.4.2	Laboratory Findings	
	7.4.3	Vital Signs	
	7.4.4	Electrocardiograms (ECGs)	
	7.4.5	Special Safety Studies/Clinical Trials	111
	7.5 Otl	her Safety Explorations	
	7.5.3	Drug-Demographic Interactions	118
	7.5.4	Drug-Disease Interactions	119
	7.5.5	Drug-Drug Interactions	119
	7.6 Ad	ditional Safety Evaluations	
	7.6.1		
	7.6.2	Human Reproduction and Pregnancy Data	
	7.6.3	Pediatrics and Assessment of Effects on Growth	
	7.6.4	Overdose, Drug Abuse Potential, Withdrawal and Rebound	124
8	POST	MARKET EXPERIENCE	125
9	APPENDICES		
	9.2 La	beling Recommendations	126
9.3 Advisory Committee Meeting			



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

