

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 1, 2015

AGENDA

Agenda: *The committee will discuss the efficacy and safety data for new drug application (NDA) 21164, gepirone hydrochloride extended-release tablets, submitted by Fabre-Kramer Pharmaceuticals, Inc., for the proposed indication of major depressive disorder.*

8:00 a.m.	Call to Order and Introduction of Committee	Ralph D'Agostino, PhD (Acting Chairperson), PDAC
	Conflict of Interest Statement	Kalyani Bhatt, BS, MS Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	John Jenkins, MD Director Office of New Drugs (OND), CDER, FDA
		Mitchell Mathis, MD Director Division of Psychiatry Products (DPP) Office of Drug Evaluation-I (ODE-I) OND, CDER, FDA
8:30 a.m.	INDUSTRY PRESENTATIONS	Fabre-Kramer Pharmaceuticals, Inc
	Introduction	Daniel Burch, MD Vice President Global Therapeutic Area Head for Neuroscience Pharmaceutical Product Development, LLC
	Rationale for Gepirone Development	Michael Thase, MD Professor of Psychiatry Perelman School of Medicine University of Pennsylvania
	Totality of Evidence for Effectiveness	Gary Koch, PhD Professor of Biostatistics and Director of Biometric Consulting Laboratory Gillings School of Global Public Health University of North Carolina at Chapel Hill
	Gepirone Clinical Experience	Stephen Stahl, MD, PhD Professor of Psychiatry University of California San Diego Founder and Director of Neuroscience Education Institute

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AGENDA (cont.)

	Conclusions	Daniel Burch, MD
10:00 a.m.	Clarifying Questions to Industry	
10:15 a.m.	BREAK	
10:30 a.m.	FDA PRESENTATIONS	
	Efficacy	Peiling Yang, PhD Biostatistics Team Leader Division of Biometrics I Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Safety	Mitchell Mathis, MD
	Substantial Evidence of Effectiveness – Office of Drug Evaluation-I Perspective	Robert Temple, MD Deputy Director for Clinical Science CDER, FDA Deputy Director (Acting) Office of Drug Evaluation-I (ODE-I) OND, CDER, FDA
	Office of Biostatistics Perspective	Lisa LaVange, PhD Director OB, OTS, CDER, FDA
11: 45 a.m.	Clarifying Questions to FDA	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Clarifying Questions to the Sponsor or FDA	
2:20 p.m.	Summary/Charge to the Committee	John Jenkins, MD
2:30 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	BREAK	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	ADJOURNMENT	