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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Ave, Silver Spring, MD
March 27, 2018

DRAFT AGENDA

The committee will discuss the new drug application (NDA) 209229, lofexidine hydrochloride, submitted by US WorldMeds, LLC, for mitigation of symptoms associated with opioid withdrawal and facilitation of completion of opioid discontinuation treatment.

8:00 a.m.	Call to Order and Introduction of Committee	**Rajesh Narendran, MD** Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	**Celia Winchell, MD** Clinical Team Leader Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**US WorldMeds, LLC.**
	Opening Remarks	**Kristen Gullo** Vice President Development & Regulatory Affairs, US WorldMeds
	Medical Landscape	**Louis Baxter, MD, DFASAM, DABAM** Executive Medical Director, Professional Assistance Program of NJ, Inc.
	Introduction to LUCEMYRA (lofexidine) Development	**Kristen Gullo**
	Lofexidine Trial Program	**Marc Fishman, MD** Medical Director, Maryland Treatment Centers Assistant Professor Johns Hopkins University School of Medicine
	Efficacy	**Charles Gorodetzky, MD, PhD** Former Medical Officer, US WorldMeds Principal Investigator, Lofexidine Clinical Trials Consultant, Pharmaceutical Medicine

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Safety	**Mark Pirner, MD, PhD** Senior Medical Director US WorldMeds, LLC
	Clinical Perspective	**Thomas Kosten, MD** Waggoner Chair and Professor of Psychiatry and Pharmacology Baylor College of Medicine
9:50 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical and Statistical Review	**Pamela Horn, MD** Clinical Reviewer DAAAP, ODE II, OND, CDER, FDA **Yi Ren, PhD** Division of Biostatistics II Office of Biostatistics Office of Translational Sciences, CDER, FDA
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committee	
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	