

**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

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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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
of Lofexidine

Pamela Horn, MD
Clinical Reviewer
DAAAP, ODE II, OND, CDER, FDA

Yi Ren, PhD
Statistical Reviewer
Division of Biometrics 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**