

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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
November 4, 2021

AGENDA

The committee will discuss new drug application (NDA) 214812, for carbetocin nasal spray, submitted by Levo Therapeutics, Inc., for the proposed treatment of hyperphagia, anxiety, and distress behaviors associated with Prader-Willi syndrome.

8:45 a.m.	Call to Order	Rajesh Narendran, MD Chairperson, PDAC
8:50 a.m.	Introduction of Committee and Conflict of Interest Statement	Joyce Frimpong, PharmD Designated Federal Officer, PDAC
9:00 a.m.	FDA Opening Remarks	Tiffany R. Farchione, MD Director Division of Psychiatry (DP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:10 a.m.	APPLICANT PRESENTATIONS	Levo Therapeutics, Inc.
	Introduction	Jay Cormier, JD, PhD Senior Vice President Levo Therapeutics, Inc.
	Unmet Medical Need	Shawn McCandless, MD Professor of Pediatrics and Head Section of Genetics and Metabolism University of Colorado School of Medicine Department Chair for Clinical Genetics and Metabolism Children's Hospital Colorado
	Efficacy	Jay Cormier, JD, PhD
	Safety	Davis Ryman, MD, PhD Vice President of Clinical Development Levo Therapeutics, Inc.

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspective

Cheri Deal, PhD, MD

Emeritus Professor, Université de Montréal
Pediatric Endocrinologist and Clinical
Investigator
Research Center, The Centre Hospitalier
Universitaire Sainte-Justine

10:40 a.m. Clarifying Questions to Applicant

11:10 a.m. **BREAK**

11:20 a.m. **FDA PRESENTATION**

Intranasal Carbetocin (LV-101) for the
Treatment of Hyperphagia Associated
with Prader-Willi Syndrome

Paul Bossie, MD

Clinical Reviewer
DP, ON, OND, CDER, FDA

Andrew Potter, PhD

Statistical Reviewer
Division of Biometrics I
Office of Biostatistics
Office of Translational Science, CDER, FDA

12:20 p.m. Clarifying Questions to FDA

12:50 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. **ADJOURNMENT**