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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center
The Great Room (Rm. 1503), Silver Spring, Maryland
March 29, 2016

DRAFT AGENDA

The committee will discuss the specific risk-benefit profile for new drug application (NDA) 207318, NUPLAZID (pimavanserin) 17 milligram (mg) immediate-release, film-coated oral tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of psychosis associated with Parkinson's disease.

8:00 a.m.	Call to Order and Introduction of Committee	**David A. Brent, MD** Chairperson, PDAC
	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	**Mitchell Mathis, MD** Director Division of Psychiatry Products (DPP) Office of Drug Evaluation I (ODE-I) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**ACADIA Pharmaceuticals Inc.**
	Introduction	**Michael Monahan, MBA, RAC** Director, Regulatory Affairs ACADIA Pharmaceuticals Inc.
	Burden of PD Psychosis and Need for Additional Treatment Options	**Stuart Isaacson, MD** Director, Parkinson's Disease and Movement Disorders Center of Boca Raton Boca Raton, Florida
	Efficacy of Pimavanserin	**Serge Stankovic, MD, MSPH** Executive Vice President, Research and Development ACADIA Pharmaceuticals Inc.
	Safety of Pimavanserin	**George Demos, MD** Executive Director, Drug Safety and Pharmacovigilance ACADIA Pharmaceuticals Inc.
	Benefit/Risk Profile	**Serge Stankovic, MD, MSPH**
	Clinician Perspective	**Clive Ballard, MD** Institute of Psychiatry King's College London London, United Kingdom
9:45 a.m.	Clarifying Questions to Applicant	

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DRAFT AGENDA (cont.)

10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Review of Pimavanserin for the Treatment of Psychosis Associated with Parkinson's Disease	**Paul Andreason, MD** Clinical Reviewer DPP, ODE-I, OND, CDER, FDA
	Mortality and Antipsychotic Drug Use in Dementia	**Marc Stone, MD** Deputy Director of Safety DPP, ODE-I, OND, 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.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	