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

Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 19, 2016

AGENDA

The committee will discuss the efficacy and safety of new drug application (NDA) 201656 (desmopressin), 0.75 mcg/0.1 mL and 1.5 mcg/0.1 mL nasal spray, submitted by Serenity Pharmaceuticals, LLC, for the proposed treatment of adult onset nocturia.

8:15 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** Chairperson, BRUDAC
	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, BRUDAC
8:30 a.m.	FDA Opening Remarks	**Hylton V. Joffe, MD, MMSc** Director, Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	**APPLICANT PRESENTATIONS**	**Serenity Pharmaceuticals, LLC**
	Introductory Remarks	**Seymour Fein, MD** Chief Medical Officer Serenity Pharmaceuticals, LLC
	Nocturia - An Unmet Medical Need	**Alan J. Wein, MD, PhD (Hon)** Founder Professor and Chair of Urology Perelman School of Medicine University of Pennsylvania
	Clinical Pharmacology and Efficacy	**Seymour Fein, MD**
	Patient Treatment Benefit Patient Reported-Outcomes	**Kristin M. Khalaf, PharmD, PhD** Assistant Director Global Health Economics and Outcomes Research Xcenda, LLC
	Integrated Summary of Safety	**Seymour Fein, MD**

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AGENDA (cont.)

APPLICANT PRESENTATIONS CONT.

	Benefit-Risk Assessment and REMS	**Annette Stemhagen, DrPH, FISPE** Senior Vice President Safety, Epidemiology, Registries and Risk Management – UBC
	Concluding Remarks	**Steven Kaplan, MD** Professor of Urology Icahn School of Medicine at Mount Sinai
9:45 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Efficacy	**Olivia Easley, MD** Medical Officer DBRUP, ODE III, OND, CDER, FDA
	An Exploratory Analysis of Clinical Meaningfulness	**Jia Guo, PhD** Biostatistician Division of Biometrics III Office of Biostatistics, OND, CDER, FDA
	Impact of Nighttime Urination (INTU) Instrument	**Sarrit Kovacs, PhD** Reviewer Clinical Outcome Assessments (COA) Staff OND, CDER, FDA
	Efficacy Summary	**Olivia Easley, MD** Medical Officer DBRUP, ODE III, OND, CDER, FDA
	Clinical Review of Safety	**Martin Kaufman, DPM, MBA** Clinical Analyst DBRUP, ODE III, OND, CDER, FDA
11:30 a.m.	Clarifying Questions to FDA	

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AGENDA (cont.)

12:00 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Clarifying Questions to Applicant or FDA

2:20 p.m. **BREAK**

2:35 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURN**