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-Outcome
Kristin M. Khalaf, PharmD, PhD
Assistant Director
Global Health Economics and Outcomes Research
Xcenda, LLC

Integrated Summary of Safety
Seymour Fein, MD
APPLICANT PRESENTATIONS cont.

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

Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) Meeting
October 19, 2016

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