

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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 9, 2018

AGENDA

The committee will discuss new drug application (NDA) 206089, oral testosterone undecanoate capsules, submitted by Clarus Therapeutics, for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

8:00 a.m.	Call to Order and Introduction of Committee	Vivian Lewis, MD Chairperson, BRUDAC
8:10 a.m.	Conflict of Interest Statement	Kalyani Bhatt, BS, MS Designated Federal Officer, BRUDAC
8:15 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
8:30 a.m.	INDUSTRY PRESENTATION	Clarus Therapeutics, Inc.
	Introduction	Robert Dudley, PhD, DABT President & CEO, Clarus Therapeutics, Inc.
	Medical Landscape	John K. Amory, MD, MPH, MS Professor of Medicine University of Washington School of Medicine Seattle, Washington
	Efficacy	Ronald S. Swerdloff, MD Distinguished Professor of Medicine David Geffen School of Medicine at UCLA Chief, Division of Endocrinology Harbor-UCLA Medical Center
	Non-Cardiovascular Safety	Theodore Danoff, MD, PhD Chief Medical Officer, Clarus Therapeutics, Inc.
	Cardiovascular Safety Assessment	William B. White, MD Professor of Medicine and Chief Hypertension and Clinical Pharmacology Division University of Connecticut Health

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AGENDA (cont.)

INDUSTRY PRESENTATION (CONT.)

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| | Safety Conclusions and Risk Management | Theodore Danoff, MD, PhD |
| | Clinical Practice Perspective | Jed Kaminetsky, MD
Clinical Assistant Professor, Department of Urology
NYU Langone Health
Medical Director, Manhattan Medical Research |
| 9:45 a.m. | Closing Comments | Robert Dudley, PhD, DABT |
| | Clarifying Questions to Industry | |
| 10:15 a.m. | BREAK | |
| 10:30 a.m. | FDA PRESENTATIONS | |
| | Ambulatory Blood Pressure Analysis | Preston Dunnmon, MD
Medical Officer
Division of Cardiovascular and Renal Products (DCRP)
ODE I, OND, CDER, FDA |
| | Additional Clinical Effects | A. Roger Wiederhorn, MD, DMSci
Medical Officer
DBRUP, ODE III, OND, CDER, FDA |
| | Dose Titration Algorithm | Dhananjay D. Marathe, PhD
Pharmacometric Reviewer
Division of Pharmacometrics (DPM)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA |
| | Bioanalysis | Chongwoo Yu, PhD
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology-III (DCP-III)
OCP, OTS, CDER, FDA |
| 11:35 a.m. | Clarifying Questions to the FDA | |
| 12:05 p.m. | LUNCH | |
| 1:00 p.m. | OPEN PUBLIC HEARING | |
| 2:00 p.m. | Clarifying Questions to Industry or FDA | |

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AGENDA (cont.)

- 2:30 p.m. **BREAK**
- 2:45 p.m. Questions to the Committee/Committee Discussion
- 5:00 p.m. **ADJOURNMENT**