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

DRAFT 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 hypogonadotropism (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.
	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
	Safety Conclusions and Risk Management	**Theodore Danoff, MD, PhD** Chief Medical Officer, Clarus Therapeutics, Inc.

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DRAFT AGENDA (cont.)

	INDUSTRY PRESENTATION (CONT.)	
	Clinical Practice Perspective	**Jed Kaminetsky, MD** Clinical Assistant Professor, Department of Urology NYU Langone Health Medical Director, Manhattan Medical Research
	Closing Comments	**Robert Dudley, PhD, DABT**
9:45 a.m.	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
11:45 a.m.	Clarifying Questions to the FDA	
12:15 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Clarifying Questions to Industry or FDA	
2:45 p.m.	**BREAK**	

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DRAFT AGENDA (cont.)

3:00 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**