

**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 10, 2018

AGENDA

The committee will discuss new drug application (NDA) 208088, oral testosterone undecanoate capsules, submitted by Lipocine Inc. 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	Lipocine Inc.
	Introduction	Mahesh Patel, PhD President and CEO Lipocine, Inc.
	TRT Overview	Adrian Dobs, MD, MHS Professor of Medicine Director, Johns Hopkins Clinical Research Network
	Efficacy	Gary Hoel, RPh, PhD Clinical Consultant, Lipocine Inc.
	Safety	Anthony DelConte, MD Chief Medical Director, Lipocine Inc.
	CV Safety	Peter A. McCullough, MD, MPH Vice Chief of Medicine and Cardiologist Baylor University Medical Center
	TLANDO in Clinical Practice	Adrian Dobs, MD, MHS
	Summary	Anthony DelConte, MD

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AGENDA (cont.)

9:45 a.m. Clarifying Questions to Industry

10:15 a.m. **BREAK**

10:30 a.m. **FDA PRESENTATIONS**

Clinical Assessment

Martin Kaufman, DPM, MBA

Clinical Analyst

DBRUP, ODE III, OND, CDER, FDA

Ex Vivo Testosterone Undecanoate To
Testosterone Conversion and Stopping
Criteria

LaiMing Lee, PhD

Clinical Pharmacology Reviewer

Division of Clinical Pharmacology III

Office of Clinical Pharmacology (OCP)

Office of Translational Sciences (OTS), CDER, FDA

11:30 a.m. Clarifying Questions to the FDA

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

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

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

2:30 p.m. **BREAK**

2:45 p.m. Questions to the Committee/Committee Discussion and Voting

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