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

DRAFT 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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DRAFT 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**	