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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
Tommy Douglas Conference Center, 10000 New Hampshire Ave, Silver Spring, MD
December 6, 2016

DRAFT AGENDA

The committee will discuss appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism while preserving or improving testicular function, including spermatogenesis.

8:00 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** (Chairperson), BRUDAC
8:10 a.m.	Conflict of Interest Statement	**CDR LaToya Bonner, PharmD, NCPS** Acting 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.	**GUEST SPEAKER PRESENTATION**	**Sergio Oehninger, MD, PhD** Professor and Vice-Chair, Department of Obstetrics and Gynecology Director, Division of Reproductive Endocrinology and Infertility EVMS Medical Group, EVMS Jones Institute for Reproductive Medicine
9:10 a.m.	Clarifying Questions to the Guest Speaker	
9:25 a.m.	**INDUSTRY PRESENTATIONS**	
	Introduction	**Michael Wyllie, PhD** Managing Director, Global Pharma Consulting, Ltd. Introduction
	Diagnostic Categories of Hypogonadism and Secondary Hypogonadal Population	**Frederick Wu, MD** Professor of Medicine and Endocrinology University of Manchester
	Treatment Considerations for Secondary Hypogonadism	**Mohit Khera, MD** Associate Professor of Urology Baylor College of Medicine
	Human Chorionic Gonadotropin	**Mohit Khera, MD**

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DRAFT AGENDA (cont.)

INDUSTRY PRESENTATIONS (CONT.)

Sperm Concentration is an Acceptable Endpoint for Demonstrating Clinical Benefit in Men who Have Hypogonadotropic Hypogonadism and Oligozoospermia (Impaired Spermatogenesis) as a Cause of Male Infertility	**Edward Kim, MD** Professor of Surgery University of Tennessee Graduate School of Medicine
Weight Associated, Secondary Hypogonadism: An acquired Estrogen-Dependent Disorder	**Andrew McCullough, MD** Director of Male Sexual Health, Urology Department Lahey Health and Medical Center
Summary and Conclusions	**Michael Wyllie, PhD**

10:25 a.m. Clarifying Questions to Industry

10:45 a.m. **BREAK**

11:00 a.m. **FDA PRESENTATIONS**

FDA Clinical Perspective on Development of Non-Testosterone Products to Treat Male Secondary Hypogonadism	**Olivia Easley, MD** Medical Officer DBRUP, ODE III, OND, CDER, FDA
A Regulatory Approach to Clinical Outcome Assessment Review for Drug Development	**Selena Daniels, PharmD, MS** Team Leader, Clinical Outcome Assessments Staff OND, CDER, FDA

11:40 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 the Guest Speaker, Industry or FDA

2:30 p.m **BREAK**

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

5:00 p.m. **ADJOURN**