

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

Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
September 9, 2014

AGENDA

The committee will discuss new drug application (NDA) 206302, nebivolol/valsartan fixed-dose combination tablets (5/80 milligrams (mg), 5/160 mg, 10/160 mg, 10/320 mg and 20/320 mg), submitted by Forest Laboratories, Inc., for the proposed indication of the treatment of hypertension.

12:00 p.m.	Call to Order and Introduction of Committee	A. Michael Lincoff, MD Chairperson, CRDAC
12:05 p.m.	Conflict of Interest Statement	Kristina A. Toliver, PharmD Designated Federal Officer, CRDAC
12:10 p.m.	FDA Introductory Remarks	Norman Stockbridge, MD, PhD Director Division of Cardiovascular and Renal Products (DCaRP) Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
12:20 p.m.	SPONSOR PRESENTATIONS	
	Introduction	Kathleen Waldron, MBA Senior Director, Regulatory Affairs Forest Research Institute, Inc.
	Background and Treatment Considerations	Michael Weber, MD, FACP, FACC, FAHA Professor of Medicine Department of Medicine, State University of New York Downstate College of Medicine Past President of the American Society of Hypertension
	Efficacy Results	David Bharucha, MD, PhD Clinical Program Lead & Senior Director, Clinical Development Forest Research Institute, Inc.
	Safety Results	Philip Hornick, MD, PhD Vice President, Clinical Development Forest Research Institute, Inc.

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AGENDA (cont.)

SPONSOR PRESENTATIONS (CONT.)

Benefits and Risks

William White, MD

Professor of Medicine

Chief, Hypertension and Clinical Pharmacology

Cardiology Center, University of Connecticut Health Center

Immediate Past President of American Society of Hypertension

1:20 p.m. Clarifying Questions to the Presenters

1:40 p.m. **FDA PRESENTATIONS**

Nebivolol/Valsartan for the
Treatment of Hypertension

George Kordzakhia, PhD

Statistical Reviewer

Division of Biometrics I

Office of Biostatistics, OTS, CDER, FDA

Rajanikanth Madabushi, PhD

Cross Disciplinary Team Leader

Clinical Pharmacology Team Leader

Division of Clinical Pharmacology I

Office of Clinical Pharmacology (OCP)

Office of Translational Sciences (OTS), CDER, FDA

2:00 p.m. Clarifying Questions to the Presenters

2:15 p.m. **BREAK**

2:30 p.m. Open Public Hearing

3:30 p.m. Questions to the Committee/Committee Discussion

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