

**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, MD  
January 14, 2014

**DRAFT AGENDA**

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*The committee will discuss New Drug Application 203202, droxidopa capsules, submitted by Chelsea Therapeutics, Inc. for the proposed treatment of symptomatic neurogenic orthostatic hypotension (nOH) in adult patients with primary autonomic failure [Parkinson's Disease (PD), Multiple System Atrophy (MSA) and Pure Autonomic Failure (PAF)], Dopamine Beta Hydroxylase (DBH) Deficiency and Non-Diabetic Autonomic Neuropathy (NDAN).*

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8:00 a.m.	Call to Order Introduction of Committee	<b>A. Michael Lincoff, MD</b> Chairperson, CRDAC
8:05 a.m.	Conflict of Interest Statement	<b>Kristina A. Toliver, PharmD</b> Designated Federal Officer, CRDAC
8:10 a.m.	Opening Remarks	<b>Norman Stockbridge, MD, PhD</b> Director Division of Cardiovascular and Renal Products (DCaRP) Office of Drug Evaluation I (ODEI) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	<b><u>Sponsor Presentations</u></b>	<b>Chelsea Therapeutics, Inc.</b>
	Introduction	<b>William D. Schwieterman, MD</b> Chief Medical Officer Chelsea Therapeutics, Inc.
	Unmet Medical Need	<b>Horacio C. Kaufmann, MD</b> Professor of Neurology and Medicine Axelrod Professor of Dysautonomia Research New York University School of Medicine
	Efficacy and Safety Results	<b>William D. Schwieterman, MD</b> Chief Medical Officer Chelsea Therapeutics, Inc.
	Cardiovascular Safety; Overall Benefit/Risk	<b>William B. White, MD</b> Professor of Medicine and Chief Division of Hypertension and Clinical Pharmacology Cardiology Center
9:50 a.m.	Clarifying Questions to the Presenters	
10:20 a.m.	<b>BREAK</b>	

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**DRAFT AGENDA (cont.)**

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10:35 a.m. **FDA Presentations**

Clinical Findings

**Shari Targum, MD**  
Clinical Team Leader  
DCaRP, ODEI, OND, CDER, FDA

Statistical Findings

**Jialu Zhang, PhD**  
Biometrics Reviewer  
Division of Biometrics I (DB-I), Office of Biostatistics (OB)  
Office of Translational Sciences (OTS), CDER, FDA

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

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

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee and Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee and Committee Discussion (cont.)

5:30 p.m. **ADJOURNMENT**