

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC)
Marriott Inn and Conference Center,
University of Maryland University College (UMUC)
East, Adelphi, Maryland
September 8, 2011

DRAFT AGENDA

The committee will discuss new drug application (NDA) 202439, rivaroxaban tablets, submitted by Johnson & Johnson Pharmaceutical Research and Development, L.L.C. on behalf of Ortho-McNeil-Janssen-Pharmaceuticals, for the prevention of stroke and systemic embolism (blood clots other than in the head) in patients with non-valvular atrial fibrillation (abnormally rapid contractions of the atria, the upper chambers of the heart).

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	A. Michael Lincoff, M.D. Acting Chair, CRDAC
	Conflict of Interest Statement	Kristina Toliver, Pharm.D. Designated Federal Officer, CRDAC
8:10 a.m.	Opening Remarks	Norman Stockbridge, M.D., Ph.D. Director, Division of Cardiovascular and Renal Products (DCRP), Office of Drug Evaluation (ODE) I, CDER, FDA
8:15 a.m.	<u>Sponsor Presentation</u>	<u>Johnson & Johnson Pharmaceutical Research and Development, L.L.C.</u>
	Introduction	Gary R. Peters, M.D. Vice President, Cardiovascular Development, Johnson & Johnson Pharmaceutical Research & Development
	Medical Landscape & Study Design	Kenneth W. Mahaffey, M.D. Co-Director, Duke Clinical Research Institute Cardiovascular Research Director, Duke Clinical Research Institute Clinical Endpoint Committee Group
	Efficacy	Robert M. Califf, M.D. Vice Chancellor Clinical Research, Duke University Medical Center Director, Duke Translational Medicine Institute
	Safety	Christopher C. Nessel, M.D. Senior Director, Clinical Research Johnson & Johnson Pharmaceutical Research & Development
	Key Issues, Benefit Risk and Conclusions	Robert M. Califf, M.D.

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DRAFT AGENDA (cont.)

9:45 a.m.	Clarifying Questions for Sponsor Presenters	
10:15 a.m.	Break	
10:30 a.m.	<u>FDA Presentation</u>	NDA 202439
	Dose Selection	Preston Dunnmon, M.D. Clinical Reviewer Division of Cardiovascular and Renal Products
	Issues Affecting Interpretation of the Efficacy Data	Martin Rose, M.D., J.D. Clinical Reviewer Division of Cardiovascular and Renal Products
11:30 a.m.	Clarifying Questions for FDA Presenters	
12:00 noon	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the CRDAC and CRDAC Discussion	
3:30 pm.	Break	
3:45 p.m.	Questions to the CRDAC and CRDAC Discussion	
5:00 p.m.	Adjourn	