

Food and Drug Administration (FDA)  
Center for Drug Evaluation and Research (CDER)  
*Cardiovascular and Renal Drugs Advisory Committee*  
*March 19, 2009*

Marriott Conference Centers,  
UMUC Inn and Conference Center by Marriott,  
3501 University Blvd., East, Adelphi, MD.

## Agenda

8:00 a.m.	Call to Order Introduction of Committee	<b>A. Michael Lincoff, M.D.</b> Acting Chair, CRDAC
	Conflict of Interest Statement	<b>Elaine Ferguson, M.S.,R.Ph.</b> Designated Federal Official, CRDAC

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*The committee will discuss new drug application (NDA) 22-406, rivaroxaban oral tablets (10 milligrams) Johnson & Johnson Pharmaceutical Research & Development, L.L.C., for the proposed indication for use in prophylaxis of deep vein thrombosis and pulmonary embolism in patients undergoing hip replacement surgery or knee replacement surgery.*

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8:05 a.m.	FDA Opening Remarks	<b>Rafel (Dwayne) Rieves, M.D.</b> Director Division of Medical Imaging and Hematology Products, CDER, OND, OODP
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8:10 a.m.	<b><u>Sponsor Presentations</u></b> Introduction	<b>Peter M. DiBattiste, M.D., F.A.C.C.</b> Cardiovascular Therapeutic Area Head Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
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	Total Hip and Knee Replacement: Current Practice	<b>Richard J Friedman MD, FRCSC</b> Charleston Orthopedic Associates Charleston, SC 29407
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	Rivaroxaban Development Program	<b>Gary R. Peters, M.D., F.A.C.P.</b> Vice President Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
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	Hepatic Safety Assessment	<b>Paul B. Watkins, M.D.</b> Verne S. Caviness Professor of Medicine Director, Hamner Center for Drug Safety Sciences University of North Carolina Chapel Hill
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	Safety Surveillance and Risk Management	<b>Peter M. DiBattiste, M.D.</b>
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	Benefit-Risk Assessment	<b>Peter M. DiBattiste, M.D.</b>
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	Summary and Conclusions	<b>Peter M. DiBattiste, M.D.</b>
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9:40 a.m. Questions to Sponsor

10:00 a.m. **Break**

### **FDA Presentations**

10:15 a.m. Overview of Prophylaxis of Deep Vein Thrombosis and Pulmonary Embolism Treatment in Patients Undergoing Hip or Knee Replacement Surgery

**Kathy Robie-Suh, M.D.**

Medical Officer/Team Leader, Division of Medical Imaging and Hematology Products, CDER, OND, OODP

10:25 a.m. Safety and Efficacy of rivaroxaban for prophylaxis in patients undergoing hip or knee replacement surgery

**Min Lu, M.D., M.P.H.**

Medical Officer, Division of Medical Imaging and Hematology Products, CDER, OND, OODP

10:55 a.m. Statistical Analysis Considerations

**Qing Xu, Ph.D.**

Statistical Reviewer, Office of Biostatistics, Division of Biometrics V

11:05 a.m. Hepatotoxicity Concerns

**Kate Gelperin, M.D., M.P.H.**

Medical Officer, Office of Surveillance and Epidemiology, Division of Epidemiology I

11:20 a.m. Dose Adjustment Considerations

**Christoffer W. Tornoe, Ph.D.**

Division of Pharmacometrics, Office of Clinical Pharmacology

11:30 a.m. Questions to FDA

12:00 **Lunch**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to Sponsor and FDA.  
Discussion of questions to committee.

3:30 p.m. **Break**

3:45 p.m. Discussion of questions to committee (continued)

5:00 p.m. Adjourn