

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.

**DRAFT 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 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, MD</b> Director Division of Medical Imaging and Hematology Products, CDER, OND, OODP
8:10 a.m.	<b><u>Sponsor Presentations</u></b>	
9:40 a.m.	Questions to Sponsor	
10:00 a.m.	<b><u>Break</u></b>	
	<b><u>FDA</u></b>	
10:15 a.m.	Overview of Prophylaxis of Deep Vein Thrombosis and Pulmonary Embolism Treatment in Patients Undergoing Hip or Knee Replacement Surgery	<b>Kathy Robie-Suh, M.D.</b> 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	<b>Dr. Min Lu, M.D.</b> Medical Officer, Division of Medical Imaging and Hematology Products, CDER, OND, OODP
10:55 a.m.	Hepatotoxicity	(Information not available at this time)
11:05 a.m.	Risk Management	<b>Kathy O'Connell, M.D.</b> Risk Management Analysts, Division of Risk Management, Office of Surveillance and Epidemiology, CDER
12:00	Questions to FDA	

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- 1:00 p.m.     **Lunch**
- 2:00 p.m.     Open Public Hearing
- 3:30 p.m.     Questions to Sponsor and FDA.  
Discussion of questions to  
committee.
- 3:45 p.m.     **Break**
- 5:00 p.m.     Discussion of questions to  
committee (continued)
- Adjourn