

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
*Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug
Safety and Risk Management Advisory Committee*

Marriott Inn and Conference Center, University of Maryland University College
(UMUC)

3501 University Blvd. East, Adelphi, Maryland

December 9, 2011

MEETING AGENDA

The Committees will discuss the benefits and risks of the Ortho Evra transdermal system (norelgestromin/ethinyl estradiol), marketed by Janssen Pharmaceuticals, Inc., for the prevention of pregnancy. Specifically, the Committees will discuss the possibly increased risk of thrombotic and thromboembolic events in users of Ortho Evra compared to women who use commonly prescribed birth control pills, as suggested by postmarketing studies.

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Valerie Montgomery Rice, M.D. Acting Chairperson, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	Kalyani Bhatt Designated Federal Officer, ACRHD
	<u>FDA Presentations:</u>	
8:10 a.m.	Opening Remarks	Scott Monroe, M.D. Director Division of Reproductive and Urologic Products (DRUP)
8:20 a.m.	Overview of Ortho Evra Systemic Exposure	Doanh Tran, Ph.D. Clinical Pharmacology Team Leader Office of Clinical Pharmacology
8:30 a.m.	Ortho Evra Compliance and Effectiveness	Daniel Davis, M.D., M.P.H. Medical Reviewer DRUP
8:40 a.m.	Ortho Evra Postmarketing Epidemiologic Studies - Overview	Rita Ouellet-Hellstrom, Ph.D. Associate Director for Science Division of Epidemiology II Office of Surveillance and Epidemiology
9:00 a.m.	<u>Guest Speaker Presentation:</u> Ortho Evra and the Risk of Cardiovascular Disease Endpoints	Stephen Sidney, M.D., M.P.H. (Guest Speaker) Associate Director for Clinical Research Division of Research Kaiser Permanente, Oakland, CA
9:15 a.m.	<u>FDA Presentation:</u> Ortho Evra Postmarketing Epidemiologic Studies - Interpretation	Rita Ouellet-Hellstrom, Ph.D.

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
*Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug
Safety and Risk Management Advisory Committee*

Marriott Inn and Conference Center, University of Maryland University College
(UMUC)

3501 University Blvd. East, Adelphi, Maryland

December 9, 2011

MEETING AGENDA (cont.)

9:45 a.m.	Clarifying Questions to the Presenters	
10:00 a.m.	BREAK	
10:15 a.m.	<u>Sponsor Presentations:</u>	<u>Janssen Pharmaceuticals, Inc.</u>
	Overview	Joanne Waldstreicher, M.D. Chief Medical Officer Janssen Research & Development, LLC
	Clinical Development and Post-Marketing Surveillance	Diane Harrison, M.D., M.P.H., FACOG Global Medical Safety Physician Janssen Research & Development, LLC
	Epidemiology	Noel Weiss, M.D., Dr.P.H. Professor of Epidemiology School of Public Health University of Washington
	Benefit/Risk Assessment	Anita Nelson, M.D., FACOG Professor of Obstetrics and Gynecology David Geffen School of Medicine University of California, Los Angeles
	Concluding Remarks	Joanne Waldstreicher, M.D.
11:45 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Risk/Benefit Analysis Summary	Lisa Soule, M.D. Clinical Team Leader DRUP
2:10 p.m.	Additional Questions to the Presenters	
2:30 p.m.	Discussion and Questions to the Committees	
5:00 p.m.	ADJOURNMENT	