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 8, 2011

AGENDA

The Committees will discuss the benefits and risks of drospirenone-containing oral contraceptives in light of the emerging safety concern that the risk of venous thromboembolism associated with use of these products may be higher compared to combination oral contraceptives that contain the progestin levonorgestrel. Drospirenone-containing oral contraceptives for the primary indication of pregnancy prevention include: YASMIN, YAZ (drospirenone/ethinyl estradiol tablets), BEYAZ, SAFYRAL (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Bayer HealthCare, and the generic equivalents for these products.

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	**Julia Johnson, M.D.** Acting Chairperson, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	**Kalyani Bhatt** Designated Federal Officer, ACRHD
	FDA Presentations:	
8:10 a.m.	Opening Remarks	**Scott Monroe, M.D.** Director, Division of Reproductive and Urologic Products (DRUP)
8:20 a.m.	Introduction and Regulatory History	**Gerald Willett, M.D.** Clinical Reviewer, DRUP
8:35 a.m.	Yasmin Postmarketing Epidemiologic Studies - Overview	**Rita Ouellet-Hellstrom, Ph.D.** Associate Director for Science Division of Epidemiology II Office of Surveillance and Epidemiology
8:55 a.m.	**Guest Speaker Presentation:** Yasmin and the Risk of Cardiovascular Disease Endpoints	**Stephen Sidney, M.D. (Guest Speaker)** Associate Director for Clinical Research Division of Research Kaiser Permanente Oakland, CA
	FDA Presentation:	
9:10 a.m.	Yasmin Postmarketing Epidemiologic Studies - Interpretation	**Rita Ouellet-Hellstrom, Ph.D.**

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9:40 a.m.	Clarifying Questions to Presenters	
10:00 a.m.	**BREAK**	
10:15 a.m.	**Sponsor Presentations:**	**Bayer Healthcare Pharmaceuticals**
10:15 a.m.	Introduction and Overview of Sponsor's Presentation	**John Talian, Ph.D.** Vice President and US Head of Regulatory Affairs, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals
10:20 a.m.	Post-Marketing Safety Studies	**Leo Plouffe, Jr., M.D., CM, FACOG** Vice President, US Medical Affairs, Women's HealthCare Bayer HealthCare Pharmaceuticals
10:45 a.m.	Scientific Assessment of the Published Observational Studies	**David Grimes, M.D., FACOG** Clinical Professor, Department of Ob Gyn University of North Carolina School of Medicine
11:00 a.m.	Scientific Assessment of the FDA-Funded Study	**Robert Makuch, Ph.D.** Professor of Biostatistics Yale University School of Medicine
11:15 a.m.	A Clinician's Perspective	**Andrea Lukes, M.D., MHSc, FACOG** Owner, Founder, Carolina Women's Research and Wellness Center , Carolina Women's Research and Wellness Center
11:30 a.m.	Conclusions and the Path Forward	**Leo Plouffe, Jr., M.D., CM, FACOG**
11:45 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	

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2:00 p.m.	Risk/Benefit Analysis Summary	**Lisa Soule, M.D.** Clinical Team Leader, DRUP
2:10 p.m.	Additional Clarifying Questions to the Presenters	
2:30 p.m.	Discussion and Questions to the Committees	
5:00 p.m.	**ADJOURNMENT**	