

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

**Cardiovascular and Renal Drugs Advisory Committee
Meeting
December 8, 2003**

Hilton, The Ballrooms, Gaithersburg, MD

8:30 - 8:45 a.m. Call to Order and Introductions	Jeffery Borer, M.D. Chair, Cardiovascular and Renal Drugs Advisory Committee
Conflict of Interest Statement	Dornette Spell-LeSane, M.H.A., NP-C Executive Secretary, FDA
8:45 - 9:00 a.m. Welcome and Introductory Comments	Douglas Throckmorton, M.D. Division of Cardiovascular and Renal Drugs, FDA

The committee will discuss whether aspirin should be recommended for primary prevention of myocardial infarction. Professional labeling for aspirin currently recommends its use for prevention of a second myocardial infarction.

9:00 a.m.	<u>Sponsor Presentation</u>	
	Introduction	Erica Peitler, RPh Bayer HealthCare LLC Morristown, NJ
	Aspirin Benefit/Risk in Primary Prevention	Thomas Pearson, M.D., M.P.H., Ph.D. University of Rochester School of Medicine, Rochester, NY
	Safety/Efficacy in Moderate Risk Population	Colin Baigent, M.D. University of Oxford Oxford, UK
	Aspirin Use in Women	C. Noel Bairey Merz, M.D. Cedars-Sinai Medical Center Los Angeles, CA

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Sponsor Presentations Cont.

Aspirin Utilization
Randall Stafford, M.D., Ph.D.
Stanford School of Medicine
Stanford, CA

Aspirin in Clinical Practice
Eric Topol, M.D.
The Cleveland Clinic Foundation
Cleveland Ohio

10:00 – 10:30 Questions

10:30 – 10:45 Break

10:45 – 11:15 **FDA Presentation**

Regulatory History of Aspirin
Michelle M. Jackson, Ph.D.
Interdisciplinary Scientist, Microbiologist
Division of Over-The-Counter
Drug Products, FDA

Statistical Analyses of the
Bayer's Citizens Petition
Chenxiong (Charles) Le, Ph.D.
Statistician
Division of Biometrics I,
Office of Biostatistics,
Office of Pharmacoepidemiology and
Statistical Science, FDA

11:15 – 12:00 Committee Discussions/Questions to the FDA

12:00 – 1:00 Lunch

1:00 – 1:30 Open Public Hearing

1:30 – 2:30 Committee Discussions

2:30 – 2:45 Break

2:45 – 4:45 Committee Questions/Summary

5:00 p.m. Adjournment