

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Cardiovascular and Renal Drugs Advisory Committee
Holiday Inn Gaithersburg
Two Montgomery Village Avenue, Gaithersburg, MD**

***AGENDA*
June 15, 2005**

The committee will discuss class labeling of antihypertensive drugs based on the proximity of their data to outcome trials

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| 8:00 | Call to Order and Introductions | Steven E. Nissen, M.D.
Committee Chair
Cardiovascular and Renal Drugs Advisory Committee |
| | Conflict of Interest Statement | LT Cathy Groupe, B.S.N.
Executive Secretary
Cardiovascular and Renal Drugs Advisory Committee |
| 8:15 | Welcome
Recognition of Retiring
Cardiovascular and Renal Drugs
Advisory Committee members | Norman Stockbridge, M.D.
Acting Director
Division of Cardiovascular and Renal Drug Products
FDA Center for Drug Evaluation and Research |
| <u>FDA Review Division Presentation:</u> | | |
| 8:30 | Introduction | Robert J. Temple, M.D.
Acting Director
Office of Drug Evaluation I
FDA Center for Drug Evaluation and Research |
| 8:45 | Applicable Outcomes Claims
For Antihypertensive Drugs | Stephen W. MacMahon, B.Sc., Ph.D., M.P.H., F.A.C.C.
Principal Director
Professor of Cardiovascular Medicine and Epidemiology
The George Institute for International Health
The University of Sydney |
| 9:00 | Differences in Outcomes Claims
For Different Drug Classes | Stephen W. MacMahon, B.Sc., Ph.D., M.P.H., F.A.C.C. |
| 9:15 | Deciding Whom to Treat
For Hypertension | Jay N. Cohn, M.D.
Professor of Medicine and Director
Rasmussen Center for Cardiovascular Disease Prevention
University of Minnesota |

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9:45	When to Initiate Successive Antihypertensive Drugs	Henry R. Black, M.D. Chairman and Associate Vice President for Research Rush University Medical Center
10:00	Can One Sustain an Outcome Claim Based on an Active Controlled Study?	
	Introduction	Lance Berman, MD Medical Director – U.S. Team Leader Pfizer, Inc.
	Methodology and Analysis [Overview]	Michael Gaffney, Ph.D. Senior Director – Statistical Research and Consulting Pfizer, Inc.
10:15		Break
10:30	Does the Pattern of Blood Pressure Effects During the Day Matter?	Thomas G. Pickering, M.D., Ph.D., F.R.C.P. Director – Integrative and Behavioral Cardiology Program The Zena and Michael A. Wiener Cardiovascular Institute Mount Sinai Medical Center
10:45	Does the Benefit Associated with Treating Hypertension Apply to Children?	Ronald J. Portman, M.D. Professor of Pediatrics and Director of the Division Pediatric Nephrology and Hypertension University of Texas – Houston Medical School
11:00		Committee Discussion
12:00		Lunch
1:00		Open Public Hearing
2:00		Committee Discussion and Questions
3:00		Break
3:15		Committee Discussion and Questions [Continued]
5:00		Adjournment