

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Cardiovascular and Renal Drugs Advisory Committee
Advisors and Consultants Staff Conference Room
DRAFT AGENDA
April 18, 2007**

*The committee will discuss supplemental new drug application (NDA 20-758/S-037), Avalide (irbesartan plus hydrochlorothiazide), Bristol-Myers Squibb Company. The sponsor is seeking approval for first-line use in hypertensive patients unlikely to achieve blood pressure goals on one drug.
The Advisory Committee will be asked to consider what constitutes adequate data to support such a claim and how the information can be most usefully displayed in labeling.*

8:00	Call to Order and Introductions	Robert A. Harrington, M.D., F.A.C.C. (Acting) Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	LCDR Cathy Groupe, M.P.H., R.N. Designated Federal Official Cardiovascular and Renal Drugs Advisory Committee
8:10	Introduction and Background	Norman Stockbridge, M.D., Ph.D. Director, Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
8:15		Open Public Hearing
8:45	<u>Sponsor Presentation – Bristol-Myer Squibb Company:</u>	
	Introduction	Anthony Waclawski, Ph.D. Vice President, Global Regulatory Sciences Bristol-Myers Squibb
	Unmet Need in Severe Hypertension	William Weintraub, M.D. John H. Ammon Chair of Cardiology and Director Christiana Center for Outcomes Research
	Discussion of Avalide Registrational Program	Pablo Lapuerta, M.D. Executive Director, Global Medical Affairs Bristol-Myers Squibb
	Benefit/Risk Profile	Michael Weber, M.D. Professor of Medicine SUNY Downstate Medical Center College of Medicine
	Conclusion	Anthony Waclawski, Ph.D.

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

**Cardiovascular and Renal Drugs Advisory Committee
Advisors and Consultants Staff Conference Room**

DRAFT AGENDA

April 18, 2007

Page 2

10:20	Questions from the Committee
10:45	Break
11:00	Committee Discussion
12:00	Lunch
1:00	Committee Discussion
2:00	Questions to the Committee
5:00	Adjournment