

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Holiday Inn**  
**Silver Spring, MD**

**CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE**

**AGENDA**  
**95<sup>th</sup> Meeting**

Thursday, January 17, 2002

- 8:30 Call to Order and Welcome: Jeffrey Borer, M.D., Chair
- 8:35 Conflict of Interest Statement: Jaime Henriquez, Executive Secretary

PRESENTATIONS:

- 8:40 NDA 20-757/S-021, Avapro® (irbesartan), Sanofi-Synthelabo (c/o Bristol-Myers Squibb), for the treatment of hypertensive patients with type 2 diabetic renal disease.

Sponsor's Presentation:

**Introduction:** Brian F. Daniels, M.D., Vice President, Pharmaceutical Research Institute, Bristol-Myers Squibb

**Disease Background:** Edmund J. Lewis, M.D., Muehrcke Professor of Nephrology and Director of the Section of Nephrology, Rush Medical College, Chicago, IL

**IDNT Efficacy and Safety:** Melisa Cooper, M.D., M.S., Vice President, Pharmaceutical Research Institute, Bristol-Myers Squibb

**IRMA 2 Efficacy and Safety:** Hans-Henrik Parving, M.D., DMSc, Professor and Chief Physician, Steno Diabetes Center, Denmark

**Benefit:Risk Assessment:** Edmund J. Lewis, M.D.

- 9:45 Break
- 10:00 Committee Discussion and Review:  
Committee Reviewer: JoAnn Lindenfeld, M.D.
- 12:00 Lunch

## CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

### AGENDA CONTINUES 95<sup>th</sup> Meeting

- 1:00 Meeting Open for Public Comments
- 2:00 Committee Discussion Continues
- 3:00 Break
- 4:30 Adjourn

#### Friday, January 18, 2002

- 8:30 Call to Order and Welcome: Jeffrey Borer, M.D., Chair
- 8:35 Conflict of Interest Statement: Jaime Henriquez, Executive Secretary
- 8:40 NDA 21-387, Pravastatin/Aspirin, Bristol-Myers Squibb, co-package, for long-term management to reduce the risk of death, nonfatal myocardial infarction, myocardial revascularization procedures, and ischemic stroke in patients with clinically evident coronary heart disease.

#### Sponsor's Presentation:

**Introduction:** Fred Fiedorek, M.D., Vice President, Bristol-Myers Squibb

**Efficacy & General Considerations:** Rene Belder, M.D., Executive Director, Bristol-Myers Squibb

**Efficacy - Meta-Analyses:** Donald A. Berry, Ph.D., Frank T. McGraw Memorial Chair of Cancer Research, University of Texas, M.D. Anderson Cancer Center

**The Medical Need:** Thomas A. Pearson, M.D., Ph.D., Albert D. Kaiser Professor of Community & Preventive Medicine, University of Rochester School of Medicine

- 9:45 Break
- 10:00 **Appropriate Dose and Relationship to Cholesterol Lowering:** Dr. Terje Pedersenm Cardiology Department, Aker University Hospital, Oslo, Norway
- 10:20 Committee Discussion and Review:  
Committee Reviewer: Alan Hirsch, M.D.
- 12:00 Lunch
- 1:00 Meeting Open for Public Comments
- 2:00 Committee Discussion Continues
- 3:00 Break
- 4:30 Adjourn

