

**Food and Drug Administration**  
**Center for Drug Evaluation and Research**

**Cardiovascular and Renal Drugs Advisory Committee**  
**97<sup>th</sup> Meeting**  
**July 19, 2002**

**Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD**

**AGENDA**

- 8:00 Call to Order and Opening Remarks Jeffrey Borer, MD, Chair  
Introduction of Committee  
Conflict of Interest Statement Jayne E. Peterson, RPh, JD,  
Acting Executive Secretary, FDA
- 8:15 NDA 21-188, VANLEV™ (omapatrilat), Bristol-Myers Squibb Company, proposed for the treatment of hypertension.

**Sponsor's Presentation**

- Introduction Anthony Waclawski, PhD  
Director, Global Regulatory Sciences,  
Pharmaceutical Research Institute,  
Bristol-Myers Squibb Company
- Clinical Efficacy Data Elliott Levy, MD  
Vice President, Clinical Development,  
Pharmaceutical Research Institute,  
Bristol-Myers Squibb Company
- Angioedema: Clinical Overview Allen Kaplan, MD  
Professor, Department of Medicine,  
Medical University of South Carolina,  
Charleston, South Carolina
- Clinical Safety Data Elliott Levy, MD
- Benefit/Risk Considerations Charles H. Hennekens, MD  
Professor of Medicine & Epidemiology/  
Public Health  
University of Miami School of Medicine
- Clinician's Perspective Henry Black, MD  
Chairman, Department of Preventative  
Medicine, Professor of Internal Medicine,  
Rush Medical College, Rush University  
Chicago, Illinois
- Conclusion Anthony Waclawski, PhD

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**AGENDA (cont.)**

- 9:15 Committee Discussion and Review  
Committee Reviewer: Steven Nissen, MD
- 10:00 Break
- 10:15 Open Public Hearing
- 10:45 Continuation of Committee Discussion and Review
- 12:00 Lunch
- 1:00 Continuation of Committee Discussion and Review
- 3:00 Adjourn

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**Meeting Guest (non-voting)**

Thomas G. Pickering, MD, DPhil  
Professor of Medicine  
Director, Integrative and Behavioral Cardiovascular Health Program  
and Hypertension Section  
Michael and Zena A. Wiener Cardiovascular Institute  
Mount Sinai School of Medicine  
One Gustave L. Levy Place  
New York, New York 10029-6574