

Food and Drug Administration
Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee
97th Meeting
July 18, 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

A.M. Session

- 8:15 NDA 20-838/S015, ATACAND® (candesartan cilexetil) Tablets,
AstraZeneca LP, for a proposed claim of comparative efficacy of candesartan
cilexetil and losartan in hypertension.

Sponsor's Presentation

- Regulatory Introduction Cindy M. Lancaster, MS, MBA, JD
AstraZeneca
- Comparison of the Antihypertensive Efficacy of Candesartan Cilexetil and Losartan Vasilios Papademetriou, MD, DSc,
FACC
Georgetown University
- Epidemiologic and Clinical Significance of Incremental Changes in Blood Pressure William B. Kannell, MD, MPH,
FACP, FACC
Boston University School of
Medicine
- Summary Cindy M. Lancaster, MS, MBA, JD
- 9:15 Committee Discussion and Review
Committee Reviewer: Paul Armstrong, MD
- 10:00 Break
- 10:15 Open Public Hearing
- 10:45 Continuation of Committee Discussion and Review
- 12:00 Lunch

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AGENDA (cont.)

P.M. Session

- 1:00 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
- 1:15 NDA 21-387, Pravastatin/Aspirin Combination Product, Bristol-Myers Squibb Company (BMS), proposed for long-term management to reduce the risk of cardiovascular events (death, nonfatal myocardial infarction, myocardial revascularization procedures, and ischemic stroke) in patients with clinically evident coronary heart disease.

Sponsor's Presentation

- Introductory Remarks Todd Baumgartner, MD
Vice President – Regulatory Sciences,
Life Cycle Management, BMS
- Pravastatin/Aspirin: Safety and Dosing Considerations Rene Belder, MD
Executive Director – Clinical Design
and Evaluation, Metabolics, BMS
- Summary Overview Fred Fiedorek, MD
Vice President – Clinical Design and
Evaluation and Exploratory Development,
BMS
- 2:15 Committee Discussion and Review
Committee Reviewer: Beverly Lorell, MD
- 3:00 Break
- 3:15 Open Public Hearing
- 3:45 Continuation of Committee Discussion and Review
- 5:00 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
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