

Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Cardiovascular and Renal Drugs Advisory Committee
98th Meeting
January 7, 2003

Holiday Inn, 8777 Georgia Avenue, Silver Spring, MD

AGENDA

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|------|-----------------------------------|--|
| 8:00 | Call to Order and Opening Remarks | Jeffrey Borer, M.D. Chair |
| | Introduction of Committee | |
| | Conflict of Interest Statement | Jayne E. Peterson, R.Ph., J.D., Acting Executive Secretary, FDA |

sNDA 20-297/S-009, Coreg® (carvedilol), GlaxoSmithKline

Proposed to reduce mortality and the risk of infarction in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction $\leq 40\%$.

8:15 **Sponsor Presentation**

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| Introduction | Clare Kahn, Ph.D. Vice President, U.S. Reg. Affairs Cardiovascular, Urogenital & Metabolic Products, GlaxoSmithKline |
| Background to the CAPRICORN Trial | Mary Ann Lukas, M.D. Senior Clinical Director, GSK |
| CAPRICORN Trial Primary Endpoints | Henry Dargie, M.D., Univ. of Glasgow Principal Investigator, CAPRICORN |
| Why are We Here? | Milton Packer, M.D., Columbia Univ. Planning Committee, CAPRICORN Principal Investigator, COPERNICUS |
| CAPRICORN Trial Effect on Non-Fatal Events | Henry Dargie, M.D. |
| Safety and Concluding Remarks | Milton Packer, M.D. |

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AGENDA (cont.)

- 9:30 Committee Discussion and Review
Committee Reviewer: Marc Pfeffer, M.D., Ph.D.
- 10:30 Break
- 10:45 Continuation of Committee Discussion and Review
- 12:00 Lunch
- 1:00 Open Public Hearing
- 2:00 Continuation of Committee Discussion and Review
- 3:15 Break
- 3:30 Continuation of Committee Discussion and Review
- 4:30 Estimated Time of Adjournment
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SGE Consultants (voting)

Thomas G. Pickering, M.D., 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
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Marc Pfeffer, M.D., Ph.D.
Professor of Medicine, Harvard Medical School
Senior Physician, Brigham & Women's Hospital
Cardiovascular Division
75 Francis Street
Boston, Massachusetts, 02115

Acting Industry Representative (non-voting)

John F. Neylan, M.D.
Vice President, Clinical Research and Development
Wyeth Research
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