

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

CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

**96th Meeting
April 12, 2002**

Holiday Inn, Silver Spring, MD

AGENDA

**NDA 20-386/S028, Cozaar™ (losartan potassium), Merck and Company, Inc.
Proposed Indication: for the treatment of type II diabetic patients with nephropathy**

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| 8:30 | Call to Order and Welcome | Jeffrey Borer, M.D., Chair |
| 8:35 | Conflict of Interest Statement | Jayne E. Peterson, R.Ph., J.D.,
Acting Executive Secretary |
| 8:40 | NDA 20-386/S028, Cozaar™ (losartan potassium), Merck and Company, Inc., for the treatment of type II diabetic patients with nephropathy. | |

Sponsor's Presentation

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| | Introduction | Michael C. Elia, Ph.D.
Director, Regulatory Affairs
Merck Research Laboratories |
| | Background, Rationale and Results of the RENAAL Study | Shahnaz Shahinfar, M.D.
Senior Director,
Cardiovascular Clinical Research
Merck Research Laboratories |
| | Review of the Evidence and Conclusions | William Keane, M.D.
Vice President, Clinical Development
Merck – US Human Health Division |
| 9:45 | Break | |
| 10:00 | Committee Discussion and Review
Committee Reviewer: JoAnn Lindenfeld, M.D. | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | Committee Discussion and Review (continuation) | |
| 3:00 | Break | |
| 4:30 | Adjourn | |