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

Cardiovascular and Renal Drugs Advisory Committee
98th Meeting
January 6, 2003

Holiday Inn, 8777 Georgia Avenue, Silver Spring, MD

AGENDA

8:30	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

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sNDA 20-386/S-032 Cozaar® (losartan potassium) Tablets, Merck and Co.

Proposed for the reduction in the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke and myocardial infarction in hypertensive patients with left ventricular hypertrophy.

8: 45 **Sponsor Presentation**

Introduction	Jeffrey R. Tucker, M.D. Director, Regulatory Affairs Merck Research Laboratories
The LIFE Study: Background, Rationale and Results	Jonathan M. Edelmann, M.D. Senior Director, Clinical Development Merck – U.S. Human Health Division
Review of the Evidence and Conclusions	William F. Keane, M.D. Vice President, Clinical Development Merck – U.S. Human Health Division

10:15 Break

10:30 **FDA Presentation**

Ethnic Subgroup Analysis from the LIFE Study	John Lawrence, Ph.D. Mathematical Statistician, FDA

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AGENDA (cont.)

11:00 Committee Discussion and Review
Committee Reviewer: Thomas Fleming, Ph.D.

12:00 Lunch

1:00 Open Public Hearing

2:00 Continuation of Committee Discussion and Review

3:00 Break

3:15 Continuation of Committee Discussion and Review

5:00 Estimated Time of Adjournment

SGE Consultant (voting)

Thomas G. Pickering, M.D., DPhil
Professor of Medicine
Director, Integrative and Behavioral Cardiovascular Health Program
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Acting Industry Representative (non-voting)

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