

Agenda - October 20, 2000 - Joint Meeting
Nonprescription Drugs & Gastrointestinal Advisory Committees
Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, 2 Montgomery Avenue, Gaithersburg, MD
Prilosec 1™(omeprazole magnesium, Astra Zeneca & Procter & Gamble, NDA 21-229)

8:00 Call to Order, Introductions

Eric Brass, M.D., Chair

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, NDAC

Introduction to the Issues

Charles Ganley, M.D., Director, DOTCDP

8 :15 Astra Zeneca and Procter & Gamble Presentations

Introduction

Douglas Ws. Bierer, Ph.D., Director, Regulatory Affairs Worldwide Personal Health Care, Procter & Gamble

Proton Pump Inhibition in the Self-Management of Heartburn

Donald O. Castell, M.D., Chairman, Department of Medicine, Graduate Hospital, Philadelphia, PA

Omeprazole-Mg OTC Efficacy Program

Nora Zorich, M.D., Ph.D., Director New Drug Development, Procter & Gamble

Consumer Usage Patterns in OTC Settings

Bernard P. Schachtel, M.D., Department of Epidemiology and Public Health, Yale University School of Medicine

Safety

Doug Levine, M.D., Chief Medical Officer, Gastrointestinal Therapeutic Area, AstraZeneca LP

Summary

Nora Zorich, M.D., Ph.D., Director New Drug Development, Procter & Gamble

9:30 Questions from the Committee to Procter and Gamble

10:00 Break

10:15 FDA Presentation

Introduction and Efficacy

Larry Goldkind, M.D., Medical Officer, DGCDP

Use Trials

Ling Chin, M.D., MPH, Medical Officer, DOTCDP

Safety

Mark Avigan, M.D., Medical Officer, DGCDP

Label Comprehension

Karen Lechter, J.D., Ph.D., DDMAC

11:30 Questions from the Committee to the FDA

12:00 Lunch

1:00 Open Public Hearing

2:00 Charge to Committee

Linda Katz, M.D., MPH, Deputy Director, DOTCDP

2:15 – 4:30 Committee Discussion