

Agenda June 21, 2002
Joint Meeting of the Nonprescription Drugs Advisory Committee with the
Gastrointestinal Drugs Advisory Committees
Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, Bethesda
Prilosec (20 mg for 14 days) for OTC use
(NDA 21-229, omeprazole magnesium, Astra Zeneca LP/Procter and Gamble)

- 8:00 Call to Order, Introductions**
Louis Cantilena, M.D., Ph.D., NDAC Chair
- Conflict of Interest Statement**
Sandra Titus, Ph.D., Executive Secretary, NDAC
- 8:15 Welcome and Introduction to Today's Issues**
Victor Raczkowski, M.D., Deputy Director, ODE II & Acting Director, Division of Gastrointestinal and Coagulation Drug Products
- 8:30 Open Public Hearing**
- 9:00 Procter and Gamble Presentations:**
- Overview**
Keith C. Triebwasser, Ph.D., Senior Director, Regulatory Affairs, Procter and Gamble
- Clinical Perspective**
David Peura, M.D., Associate Chief of Gastroenterology, University of Virginia
- Efficacy and Consumer Use**
Douglas Ws. Bierer, Ph.D., Director OTC Drug Development, Procter and Gamble
- Safety Update in the OTC Setting**
Douglas Levine, M.D., Chief Medical Officer, Gastrointestinal Therapeutic Area, AstraZeneca LP
- Benefit/Risk**
Nora Zorich, M.D., Ph.D., Vice President Pharmaceuticals, Procter & Gamble
- Summary**
Keith C. Triebwasser, Ph.D.,
- 10:00 Questions from the Committee to Procter and Gamble**
- 10:30 Break**
- 11:00 FDA Presentations:**
- Summary of 2000 NDAC/GIAC meeting on Prilosec and Overview of Efficacy**
Mark Avigan, M.D., Medical Officer, Division of Gastrointestinal and Coagulation Drug Products
- Label Comprehension Studies**
Karen Lechter, J.D., Ph.D., Office of Drug Safety
- Actual Use Study**
Daiva Shetty, M.D., Medical Officer, Division of Over the Counter Drugs
- 11:45 Questions from the Committee to the FDA**
- 12:30 Lunch Break**
- 1:30 Charge to the Committee**
Linda Katz, M.D., MPH, Deputy Director, Division of Over-the Counter Drugs
- 5:00 Adjourn**