

Draft Agenda
September 19, 2002
Nonprescription Drugs Advisory Committee
Food and Drug Administration
Center for Drug Evaluation and Research
Hilton Hotel, Silver Spring Maryland
8727 Colesville Road
Safety Issues Related to Acetaminophen

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

Charles Ganley, M.D., Director, Division of Over-the-Counter Drug Products

Overview of Acetaminophen Labeled Warnings

William Gilbertson, Pharm.D., Associate Director of Drug Monographs,
Over-the-Counter Drug Products

8:45 FDA Acetaminophen Presentations

Acetaminophen Variability in Absorption and Metabolism

John Senior M.D., Senior Scientific Advisor, Office of Drug Safety

Acute Liver Failure in the US: Results of the US ALF Study Group

Will Lee, M.D., University of Texas Southwestern Medical Center at Dallas

Epidemiology and Public Health Impact

Parivash Nourjah, Ph.D., Epidemiologist, Office of Drug Safety

Literature Review and Poison Control Data

Rizwan Ahmad M.D., M.P.H., Epidemiologist, Office of Drug Safety

FDA Adverse Event Reports (AERs)

Claudia Karwoski, Pharm.D., Team Leader, Office of Drug Safety

9:45 Questions to FDA

10:10 Break

10: 30 Open Public Hearing – Industry Presentations

McNeil

5 minutes - Introduction

Debra Bowen, M.D., Vice President, Research & Development

15 minutes - Acetaminophen Metabolism and Pharmacokinetics

John Slattery, Ph.D., Professor of Pharmaceutics, University of Washington

15 minutes - Assessment of Acetaminophen Safety

Richard Charles Dart, M.D., Ph.D., Director, Rocky Mountain Poison & Drug Center, Colorado

15 minutes - Acetaminophen Use in Selected Populations

Raymond S. Koff, M.D., Director of Clinical Hepatology Research, U of Massachusetts

5 minutes - Analgesic Benefit

Daniel B. Carr, M.D., Department of Anesthesia, Tufts New England Medical Center

5 minutes - Summary & Q&A

Anthony R. Temple, M.D., Vice President, Medical & Regulatory Science

11:20 Wyeth: Acetaminophen Background Rebuttal

Stephen Cooper, M.D., Senior Vice-President for Global Clinical and Medical Affairs

11:25 Bayer: OTC Acetaminophen Safety

Allen H. Heller, M.D., Vice President and Head Global Research & Development, Bayer

11:35 Questions to the Presenters

12:00 Lunch

1:00 Open Public Hearing – Public Presentations

10 minutes Sarah Erush, Pharm.D. and Karen Shalaby, Pharm D, University of Pennsylvania

5 minutes Susan Bishop, American Pharmaceutical Association

5 minutes Ray Bullman, National Council on Patient Information & Education

5 minutes Ms. Kate, Pennsylvania

5 minutes Caroline Riely, M.D., American Liver Foundation

5 minutes Peter Lurie, M.D., M.P.H, Assistant Director, Public Citizen Health Research Group

5 minutes Louis Lasagna, M.D., Tufts University

1:45 Committee Discussion

5:00 Approximate Time of Adjournment