

# **Final Agenda (revised to reflect the changes) September 20, 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 ASA and NSAIDs**

#### **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 Asprin and NSAID Labeled Warnings**

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

#### **8:40 Open Public Hearing – Public Presentations**

Rebecca Burkholder, National Consumers League

#### **8:50 FDA Presentations**

##### **OTC NSAID and ASA GI Bleeding: Analysis of Spontaneous Reports**

Joyce Weaver, Pharm.D., Office of Drug Safety

##### **Risk of NSAIDs: Focus on GI Risks of Over-the-Counter NSAIDs**

Byron Cryer, M.D., University of Texas Southwestern Medical School

##### **OTC NSAIDs and Nephrotoxicity**

Juan Carlos Pelayo, M.D., Division of Cardio-Renal Drug Products

##### **NSAIDs and Gastrointestinal and Renal Complications: Lessons from Tennessee Medicaid Population Studies**

Marie Griffin, M.D., Vanderbilt University, Nashville, Tennessee

#### **9:50 Questions to FDA**

#### **10:15 Break**

#### **10:30 Open Public Hearing – Industry Presentations**

##### **Bayer Presenters– 30 minutes**

##### **3 minutes - Introduction**

Allen H. Heller, M.D., Bayer Consumer Care Division

##### **10 minutes - Overview of Safety Assessment**

Gerald A. Faich, M.D., M.P.H, Consultant, Philadelphia, PA

##### **15 minutes - Risk-Benefit of CV Uses of Aspirin**

Charles H. Hennekens, M.D., Dr.P.H, Visiting Professor of Medicine, Epidemiology & Public Health, University of Miami

##### **2 minutes - Conclusions**

Allen H. Heller, M.D., Bayer Corporation, Consumer Care Division

#### **11:15 Questions to Bayer**

#### **11:30 Wyeth Presenters**

**5 minutes - Safety/Labeling**

Roger G. Berlin, M.D., FACP, FACG , President Global Scientific Affairs

**5 minutes - Renal considerations for NSAID's**

Domenic A. Sica, M.D., School of Medicine, Medical College of Virginia Commonwealth University, Medicine and Pharmacology Department of Internal Medicine/Nephrology/Pharmacology & Toxicology

**5 minutes - GI/Renal toxicity (adults Vs younger populations)**

Philip Walson, M.D., Professor, Pediatric Pharmacology & Pharmacy, University of Cincinnati

**5 minutes - Potential toxicity relative to overdose**

Richard Weisman, Pharm. D., Director, Florida Poison Control Center – Miami

**11:50 Questions to Wyeth Presenters**

**12:00 McNeil Presenters**

**10 - Review of Epidemiological Data on Aspirin and Other NSAID's**

Kenneth J. Rothman, Dr.PH. , Professor, Epidemiology & Biostatistics, Boston University School of Public Health

**12:10 International Ibuprofen Association**

Michael Langman, M.D., University of Birmingham

Nicholas Moore, Professor of Clinical Pharmacology, CHU de Bordeaux, France

**12:20 Questions to McNeil and International Ibuprofen**

**12:30 Lunch**

**1:30 Committee Discussion**

**6:00 Meeting adjourned**