

**Agenda April 22, 2002**

**Nonprescription Drugs Advisory Committee with consultants from  
Pulmonary - Allergy and Dermatologic Drugs Advisory Committees**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Holiday Inn, Bethesda

**Claritin for OTC use  
(NDA 19-658, NDA 20-704 and NDA 20-641, loratadine, Schering – Plough)**

**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, Over-the-Counter Drugs

**8:30 Schering Plough Presentations:**

**Overview**

John Clayton, Ph.D, Senior VP Scientific and Regulatory Affairs

**Clinical Overview of Urticaria**

Eugene W. Monroe, M.D., Department of Dermatology, Medical College of Wisconsin

**Schering Studies on CIU**

Stephen Neuman, Senior Director, Marketing Support Services

**Risk-Benefit Analysis on CIU**

John Clayton, Ph.D.

**9:30 Questions from the Committee to Schering Plough**

**10:00 Break**

**10:30 FDA Presentations:**

**Urticaria An Overview and OTC Considerations**

Jonathan Wilkin, M.D., Director, Dermatologic Drugs

**Clinical Study Design Issues for the Approved H1 Antihistamines with CIU Indication**

Badrul Chowdhury, M.D., Ph.D., Team Leader, Pulmonary and Allergy Drugs

**OTC Issues: US Regulatory History, Foreign Marketing and Label Comprehension Study**

Matthew Holman, Ph.D., Interdisciplinary Scientist, Over-the-Counter Drugs

**Summary of Issues on Urticaria as an OTC indication**

Charles Ganley, M.D.

**11:30 Questions from the Committee to the FDA**

**12:00 Lunch Break**

**1:00 Open Public Hearing**

**2:00 Committee Discussion**

**5:00 Adjourn**