

**Agenda May 11, 2001**  
**Joint Meeting - Nonprescription Drugs Advisory Committee &  
Pulmonary - Allergy Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Gaithersburg, MD

**Petition 98P-0610/CP1 - submitted by Blue Cross of California requesting  
fexofenadine hydrochloride, loratadine and cetirizine hydrochloride to OTC status**

**8:00 Call to Order, Introductions**

Eric Brass, M.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 Drugs

**8:30 Blue Cross Petition**

Robert Seidman, PharmD., M.P.H., Vice President, Wellpoint Health Networks, Pharmacy Department

Michael Nichol, Ph.D., University of Southern California, School of Pharmacy

Jack Kern, Pharm.D., University of Southern California, School of Pharmacy

**9:00 Questions from the Committee to Blue Cross**

**9:15 Response to Petition by Aventis**

Francois Nader, M. D., Senior Vice President of Medical and Regulatory Affairs, Aventis

**9:30 Response to Petition by Schering-Plough**

Robert Spiegel, M.D., Sr.V.P. Medical Affairs, Chief Medical Officer; Schering Plough Research Institute

**9:45 Questions from the Committee to Aventis , Schering-Plough and Pfizer**

**10:00 Break**

**10:15 Open Public Hearing**

**11:00 FDA Presentation**

**OTC Considerations**

Cazemiro Martin, Division of Over-the-Counter Drugs

**Clinical Safety Overview**

Robert Meyer, M.D., Director, Division of Pulmonary and Allergy Drugs

**11:45 Questions from the Committee to the FDA**

**12:00 Lunch Break**

**1:00 Open Public Hearing**

**2:00 Committee Discussion**

**5:00 Adjourn**