

## **Gastrointestinal Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research

Holiday Inn, 8777 Georgia Ave., Silver Spring, MD

### **Chemoprevention of Colorectal Cancer**

#### **Agenda for March 19, 2002**

- 8:00 Call to Order, Introductions:** M. Michael Wolfe, M.D., Chair
- Meeting Statement:** Thomas H. Perez, M.P.H., Executive Secretary
- Opening Comments:** Victor F.C. Raczkowski, M.D., M.Sc.  
Acting Director, Division of Gastrointestinal and Coagulation Drug Products
- 8:15 Epidemiology and Mechanisms of Colorectal Cancer** - - Anil K. Rustgi, M.D., T.Grier Miller Associate Professor of Medicine and Genetics; University of Pennsylvania
- 8:45 Colorectal Cancer Screening and Surveillance** - - David A. Lieberman, M.D., Chief, Division of Gastroenterology, Oregon Health Sciences University
- 9:15 Overview of Chemoprevention Trials** - - Bernard Levin, M.D., Vice President for Chemoprevention, Professor of Medicine, UTMD Anderson Cancer Center
- 9:45 Benefit and Risk Analysis for Chemoprevention of Sporadic Colorectal Cancer** - - Mark Avigan, M.D., C.M., Medical Officer, Division of Gastrointestinal and Coagulation Drug Products
- 10:15 Break**
- 10:30 Questions Regarding Presentations**
- 11:00 Open Public Hearing**
- 12:00 Lunch**
- 1:00 Introduction to Questions** - - Mark Avigan, M.D., C.M.  
Medical Officer, Division of Gastrointestinal & Coagulation Drug Products
- 1:10 Charge to the Committee** - - Victor F.C. Raczkowski, M.D., M.Sc.  
Acting Director, Division of Gastrointestinal & Coagulation Drug Products
- 1:20 Discussion of Questions**
- 3:15 Break**
- 3:30 Discussion of Questions – continued**
- 5:30 Adjourn**

**Consultants:**

Curt D. Furberg, M.D.  
Professor, Department of Public Health Sciences  
Wake Forest University School of Medicine

Scott Lippman, M.D.  
UT MD Anderson Cancer Center

Nancy A. Roach, Patient Representative

**Guest Experts:**

Bernard Levin, M.D.  
Vice President for Chemoprevention  
Professor of Medicine, UTMD Anderson Cancer Center

John A. Baron, M.D.  
Professor of Medicine, Community and Family Medicine  
Dartmouth Medical School

David F. Ransohoff, M.D.  
University of North Carolina at Chapel Hill

Alex Krist M.D.  
Dept. of Family Practice  
Virginia Commonwealth University

Barnett Kramer, M.D.  
Associate Director for Disease Prevention  
Office of Disease Prevention, National Institutes of Health

Anil K. Rustgi, M.D.  
Chief of Gastroenterology  
University of Pennsylvania

David A. Lieberman, M.D.  
Chief, Division of Gastroenterology  
Oregon Health Sciences University

**Industry Representative:**

George S. Goldstein, M.D.

**Open Public Hearing Participants:**

Robert Sandler, M.D.,  
Professor of Medicine and Epidemiology  
University of North Carolina at Chapel Hill

Sylvia Kleiman