

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

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