

Gastrointestinal Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research

Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD
Risk management for (NDA) 21-107, Lotronex™ (alosetron), GlaxoSmithKline

Agenda for April 23, 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:** Florence Houn, M.D., M.P.H., Director, Office of Drug Evaluation III
Paul Seligman, M.D., Director,
Office of Pharmacoepidemiology and Statistical Science
- 8:15 GlaxoSmithKline Presentation**
- | | |
|---|--------------------------|
| Introduction | James B.D. Palmer, M.D. |
| Burden of Illness & Efficacy of Alosetron | Peter Traber, M.D. |
| Safety Assessment & Benefit Risk Overview | Eric Carter, M.D., Ph.D. |
| Proposed Risk | David Wheadon, M.D. |
| Management Plan Clinician's Perspective | Robert Sandler, M.D. |
| Summary and Conclusions | James B.D. Palmer, M.D. |
- 9:45 Break**
- 10:00 FDA Presentation**
- | | |
|---|----------------------------|
| Introduction | Victor Raczkowski, M.D. |
| Lotronex: Clinical Trial Experience | Thomas Permutt, Ph.D. |
| Post-Marketing Experience with Lotronex | Ann Corken Mackey, M.P.H. |
| Risk-Benefit Issues | Victor Raczkowski, M.D. |
| Lotronex Risk-Management Program | Toni Piazza-Hepp, Pharm.D. |
| Summary and Conclusions | Victor Raczkowski, M.D. |
- 11:00 Questions on Presentations**
- 11:20 Break**
- 11:30 Open Public Hearing**
- 1:00 Lunch**
- 1:45 Introduction to Questions & Charge to the Committee** Victor Raczkowski, M.D.
- 1:55 Discussion of Questions**
- 3:30 Break**
- 3:40 Discussion of Questions – continued**
- 5:00 Adjourn**

Advisory Committee for Pharmaceutical Science members (Voting)

Gloria Anderson, Ph.D., Fuller E. Callaway Professor of Chemistry, Morris Brown College

Jurgen Venitz, M.D., Ph.D., Dept. of Pharmaceutics, School of Pharmacy, Medical University of Virginia

Consultants (Voting)

Peter Gross, M.D., Department of Internal Medicine, Hackensack University Medical Center

Brian L. Strom, M.D., M.P.H., Dept. Biostatistics & Epidemiology, Philadelphia College of Pharmacy

Ruth S. Day, Ph.D., Duke University

Jacqueline Gardner, Ph.D., MPH., Department of Pharmacy University of Washington,

Eric S. Holmboe, M.D., Yale University School of Medicine

William H. Campbell, Ph.D., University of North Carolina at Chapel Hill

Stephanie Y. Crawford, Ph.D., College of Pharmacy University of Illinois at Chicago

Michael R. Cohen, R.Ph., M.S., D.Sc., Institute for Safe Medication Practices

Thomas Fleming, Ph.D., Professor and Chair Department of Biostatistics

Arthur Levin, M.P.H., Center for Medical Consumer & Health Care Information

Guests & Guest Experts (Non-voting)

Carlar Blackman, Center for Functional GI and Motility Disorders, University of North Carolina

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

Industry Representatives:

George S. Goldstein, M.D.

John T. Sullivan, M.D.

Open Public Hearing Participants:

Sidney M. Wolfe, M.D. Public Citizen's Health Research Group

Nancy Norton Int. Foundation for Functional GI Disorders

Jeffrey D. Roberts IBS Help Group

Corey Miller Lotronex Action Group

Gary C. Stein, Ph.D. American Society of Health-System Pharmacists

William Brown, Esq.

Lisa Kenney

Maria Zargo

Julia R. Alberino

Terry Olifiers

Diana Hoyt

Lee & Virginia McLendon

Cynthia Huschles

Kathleen Kelly Ghawi

Terry Romeo

Mike Schmidt

Brenda & Franklin Compton

Dennis K. Larry, Esq.