Gastrointestinal Drugs Advisory Committee & Drug Safety and Risk Management Subcommittee of the Advisory Committee for Pharmaceutical Science

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., M.P.H., 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**	
9:55	**FDA Presentation**	
	Introduction	Victor Raczkowski, M.D.
	Lotronex: Clinical Trial Experience	Thomas Permutt, Ph.D.
	Post-Marketing Experience with Lotronex	Ann Corken Mackey, R.Ph., 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.
10:55	**Questions on Presentations**	
11:15	**Break**	
11:25	**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**	