

**Agenda: April 10, 2000**

**Urology Subcommittee for the  
Advisory Committee for Reproductive Health Drugs  
Holiday Inn, Bethesda, MD**

**Issue: Safety and Effectiveness of Uprima<sup>®</sup> (NDA 21-118), Tap Holdings**

**9:00 Call to Order, Introductions**

Ricardo Azziz, M.D., M.P.H., Subcommittee Chair

**Conflict of Interest Statement**

Jayne Peterson, R.Ph., J.D., Executive Secretary, ACRHD

**9:10 Tap Holdings Presentations**

**Introduction**

James Freston, M.D., Ph.D., University of Connecticut Health Center

**Pharmacokinetics and Metabolism**

Barbara Bopp, Ph.D., Manager, Drug Metabolism & Pharmacology, Tap Holdings

**Erectile Dysfunction Treatments and Summary of Efficacy**

Jeremy Heaton, M.D., Professor, Queens University, Ontario, Canada

**Summary of Safety**

James Freston, M.D., Ph.D. and Timothy Fagan, M.D., Professor, University of Arizona

**Benefit-Risk Assessment and Summary**

James Freston, M.D., Ph.D.

**10:30 Break**

**10:45 FDA Presentations**

**Overview**

Daniel Shames, M.D., Urology Team Leader, Division of Reproductive and Urologic Drug Products (DRUDP)

**Pharmacokinetics and Drug-Alcohol Interactions**

Venkateswar Jarugula, Ph.D., Clin. Pharmacology and Biopharmaceutics Reviewer, DRUDP

**Clinical Safety and Efficacy**

Mark Hirsch, M.D., Medical Officer, DRUDP

**Drug - Antihypertensive Interactions and Summary**

Marianne Mann, M.D., Deputy Director, DRUDP

**12:00 Lunch**

**1:00 Open Public Hearing**

**2:00 Advisory Subcommittee Discussion of Questions**

**5:30 Adjourn**