

Agenda
Thursday, April 29, 1999
Peripheral and Central Nervous System Advisory Committee

Issue: Safety and Efficacy of Freedox® (tirilazad mesylate Injection (NDA 20-399))

8:30 **Call to Order, Introductions**
Sid Gilman, M.D., Chair, PCNS

Conflict of Interest Statement
Sandra Titus, Ph.D., Executive Secretary, PCNS

8:40 **FDA Introduction**
Russell Katz, M.D., Acting Director, Neuropharmacological Drug Products

Efficacy Data
Armondo Oliva, M.D., Medical Officer, ODE 1

Safety Data
Judith A. Racoosin, M.D., MPH, Medical Officer, ODE 1

10:10 Break

10:30 **Pharmacia and Upjohn Presentations**

Introduction: SAH Development Program: Past and Present Issues
Mark Corrigan, M.D., VP, Global Clinical Development, Pharmacia and Upjohn

Risk Benefit Assessment: SAH: Response to Specific FDA Comments
Lawrence Marshall, M.D., Professor & Chief Division of Neurological
Surgery, University of California San Diego

Concluding Remarks
Mark Corrigan, M.D., VP, Global Clinical Development, Pharmacia and Upjohn

12:00 **Lunch**

1:00 **Open Public Hearing**
PD Dr.med. Hans Landolt, Head of Clinic, Kantonsspital, Switzerland

2:00- 5:00 **Discussion by Advisory Committee**

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PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE
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