

**Proposed Agenda: Friday, January 28, 2000
Peripheral and Central Nervous System Drugs
Advisory Committee**

**Food and Drug Administration
Hilton, Gaithersburg, Maryland**

8:00 Call to Order, Introductions
Sid Gilman, M.D., Chair, PCNS

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

**Consideration of NDA 21-120, Novantrone® (mitoxantrone hydrochloride) Immunex
Proposed indication: To slow progression of neurological disability and reduce the
relapse rate in patients with progressive multiple sclerosis**

8:15 FDA Overview of Issues
Overview of Issues, M.D., Director, Neuropharmacological Drug Products

8:45 Immunex Presentations

Introduction
Ann Hayes, M.D., Senior Vice President Medical Development

Efficacy and Safety
Richard Ghalia, M.D., Senior Director Clinical Development

Conclusion
Fred Lublin, M.D., Professor of Neurology, MCP Hahnemann University

10:15 Break

10:30 Questions from Advisory Committee to Immunex and to FDA

11:30 Lunch

1:00 Open Public Hearing

2:00 – 4:30 Continued Committee Discussion and Deliberation