

**Final Agenda: Wednesday November 3, 1999
Psychopharmacologic Drugs Advisory Committee**

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

8:00 Call to Order, Introductions

Carol Tamminga, M.D., Chair, PDAC

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, PDAC

Welcome

Russell Katz, M.D., Director, Neuropharmacological Drug Products

**Consideration of NDA 18-936 (S), Prozac® (fluoxetine hydrochloride) Eli Lilly & Co.
Proposed indication: Treatment of Premenstrual Dysphoric Disorder**

8:15 FDA Overview of Issues

Thomas Laughren, M.D., Team Leader, Psychiatric Drug Products Group

8:30 Lilly Presentations

Introduction

Gregory T. Brophy, Ph.D., Director, US Regulatory Affairs

Overview of PMDD

Jean Endicott, Ph.D., Department of Psychiatry, Columbia University, New York

Efficacy and Safety of Fluoxetine in PMDD

Rajinder Judge, M.D., Medical Director, Neurosciences, Eli Lilly & Co.

10:00 Break

10:15 Questions from Advisory Committee to Lilly and to FDA

11:30 Lunch

1:00 Open Public Hearing

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