Minutes: November 3, 1999
Psychopharmacological Drugs Advisory Committee

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

The meeting was held at the Hilton in Gaithersberg Maryland. Prior to the meeting, the members, consultants and guests had reviewed background material from the FDA and from Lilly. There were approximately 150 persons in attendance.

Attendance:
PDAC Members Present: Carol Tamminga, M.D., Roberto Dominguez, M.D., Abby Fyer, M.D., Barbara Geller, M.D., Edwin Cook, M.D., Andrew Winokur, M.D., Ph.D.,Robert Hamer, Ph.D.

PDAC Members Absent: Gaurdia Banister, Ph.D.,

PDAC Guest: Marty Altemus, M.D., Susan Thys-Jacobs, M.D., Barbara Parry, M.D.

FDA Participants: Robert Temple, M.D., Russell Katz, M.D, Thomas Laughren, M.D., Susan Molchan, M.D., Y. Richard Chen, Ph.D.

Overview of FDA's Presentation:
Thomas Laughren, M.D., gave an overview of the FDA issues.

Overview of Lilly's Presentation:
Gregory T. Brophy, Ph.D., Director, US Regulatory Affairs gave the introduction. Jean Endicott, Ph.D., Department of Psychiatry, Columbia University, New York gave an overview of PMDD. Rajinder Judge, M.D., Medical Director, Neurosciences, Eli Lilly & Co. presented the studies on Efficacy and Safety of Fluoxetine in PMDD.

Open Public Hearing:
Society for Women's Health Research made a statement.

Discussion:

There was consensus among committee members that PMDD is a recognized clinical entity that is well-defined and has accepted diagnostic criteria. The view of most members was the PMDD is distinct from major depressive disorder and should be labeled separately from the depressive disorders.

Following a discussion dealing with general issues regarding PMDD research and specifically about this NDA the committee voted on the following questions:

QUESTIONS REQUIRING A VOTE OF THE PDAC:

1. Has the sponsor provided evidence from more than one adequate and well controlled clinical investigation that supports the conclusion that Fluoxetine is effective for the treatment of Premenstrual Dysphoric Disorder?

Yes = 7 **No = 0**

2. Has the sponsor provided evidence that Fluoxetine is safe when used in the treatment of PMDD?

Yes = 7 **No = 0**

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

I certify that I attended the November 3, 1999 meeting of the Psychopharmacologic Drugs Advisory Committee and that these minutes accurately reflect what transpired.

Sandra Titus 4 Nov 1999 Carol Tamminga MD 15 Nov 1999

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

Carol Tamminga, M.D. Date
Chair, PDAC