

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Drug Evaluation and Research (CDER)**  
**PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE**  
**Hilton Hotel, The Ballrooms, Gaithersburg, MD**  
**8:00 a.m. – 5:00 p.m.**  
**December 2, 2005**

*AGENDA*

The Committee will discuss new drug application ([NDA] 21-514), Daytrana™ (methylphenidate transdermal system), formerly proposed as Methypatch®, Shire Pharmaceuticals and Noven Pharmaceuticals, Inc. Proposed indication is for the treatment of attention deficit hyperactivity disorder (ADHD).

---

8:00 a.m.	Call to Order and Opening Remarks	Wayne K. Goodman, M.D. Chair, Psychopharmacologic Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Cicely C. Reese, Pharm.D. Executive Secretary
8:10 a.m.	FDA Introductory Remarks	Thomas Laughren, M.D. Director, Division of Psychiatry Products, CDER, FDA
	FDA Overview	Paul Andreason, M.D. Deputy Director, Division of Psychiatry Products, CDER, FDA
8:30 a.m.	<b>FDA Presentation</b>	Robert Levin, M.D. Medical Officer Division of Psychiatry Products, CDER, FDA
9:15 a.m.	<b>Sponsor Presentation</b>	
	Introduction	Douglas Hay, Ph.D. Senior Vice President Global Regulatory Affairs Shire Pharmaceuticals
	ADHD: Current Treatment	Marc Lerner, M.D. Clinical Professor of Pediatrics University of California, Irvine
	Clinical Efficacy of MTS in Children with ADHD	Liza Squires, M.D. Senior Director Global Clinical Medicine Shire Pharmaceuticals
	MTS Safety Evaluations	Raymond Pratt, M.D. Shire Pharmaceuticals

MTS: Clinical Perspective

Sharon Wigal, Ph.D.  
Associate Clinical Professor of Pediatrics  
University of California, Irvine

Benefit/Risk Summary

Raymond Pratt, M.D.  
Shire Pharmaceuticals

10:45 a.m. Break

11:00 a.m. **Questions from the Committee to FDA and Sponsor**

12:00 p.m. Lunch

1:00 p.m. **Open Public Hearing**

2:00 p.m. **Committee Discussion**

3:00 p.m. Break

3:15 p.m. **Questions to the Committee**

Summary

5:00 p.m. **Adjournment**

---

***MEETING ROSTER***  
**PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE**  
**December 2, 2005**

Committee Members:

Jean Bronstein, R.N., M.S.

Wayne Goodman, M.D.

Andrew C. Leon M.D.

Daniel S. Pine M.D.

Bruce Pollock, M.D., Ph.D.

Delbert Robinson, M.D.

Philip Wang, M.D., Dr.P.H.

Barbara Wells, Pharm.D.

Temporary Voting Members:

Deborah Dokken MPA

Barbara Geller, M.D.

Richard Malone, M.D.

Cynthia Pfeffer, M.D.

Non-Voting Member

Dilip Mehta, M.D., Ph.D.

FDA Participants (Non-Voting):

Robert Temple, M.D.

Thomas Laughren, M.D.

Paul Andreason, M.D.

Robert Levin, M.D.