

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.
March 23, 2006

AGENDA

The Committee will discuss new drug application (NDA) 20-717/ S -019, trade name Provigil® Tablets, Cephalon, Inc., proposed indication is for 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
8:05 a.m.	FDA Introductory Remarks	Thomas P. Laughren, M.D. Director, Division of Psychiatry Products, CDER, FDA
8:10 a.m.	FDA Presentation	
	FDA Clinical Review	Glenn Mannheim, M.D. Medical Officer, Division of Psychiatry Products, CDER, FDA
8:40 a.m.	Modafinil for the Treatment of ADHD	Paul J. Andreason, M.D. Deputy Director, Division of Psychiatry Products, CDER, FDA
8:55 a.m.	Serious Adverse Cutaneous Reactions to Drugs	Michael E. Bigby, M.D. Associate Professor Beth Israel Deaconess Medical Center
9:15 a.m.	Sponsor Presentation	
	Introduction	Victor Raczkowski, M.D. Vice President Worldwide Regulatory Affairs Cephalon, Inc.
	Overview of ADHD	Joseph Biederman, M.D. Professor of Psychiatry Massachusetts General Hospital and Harvard Medical School
	Clinical Pharmacology and Efficacy	Lesley Russell, M.R.C.P. Senior Vice President Worldwide Clinical Research Cephalon, Inc.

	General Safety	Srdjan Stankovic, M.D Vice President Neuroscience Clinical Research Cephalon, Inc.
	Benefit-Risk/Conclusions	Lesley Russell, M.R.C.P. Senior Vice President Worldwide Clinical Research Cephalon, Inc.
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
March 23, 2006

<u>Committee Members:</u>	<u>Temporary Voting Members:</u>	<u>FDA Participants (Non-Voting):</u>
Jorge Armenteros, M.D.	Michael Bigby, M.D.	Robert Temple, M.D.
Jean Bronstein, R.N., M.S.	Deborah Dokken, MPA	Thomas P. Laughren, M.D.
Wayne K. Goodman, M.D.	Richard Malone, M.D.	Paul J. Andreason, M.D.
Andrew C. Leon M.D.	Cynthia Pfeffer, M.D.	Glenn Mannheim, M.D.
Daniel S. Pine M.D.	Marsha Rappley, M.D.	
Delbert Robinson, M.D.	<u>Non-Voting Member</u>	
Philip Wang, M.D., Dr.P.H.	Dilip Mehta, M.D., Ph.D.	
Barbara Wells, Pharm.D.		