

**Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

Peripheral and Central Nervous System Drugs Advisory Committee

September 25, 2003

*Holiday Inn
8120 Wisconsin Avenue, Bethesda, Maryland*

Draft AGENDA

8:00	Call to Order and Opening Remarks	Claudia Kawas, MD Chair
	Introduction of Committee	
	Conflict of Interest Statement	Anuja M. Patel, M.P.H. Executive Secretary, FDA

On September 25, the committee will discuss supplementary new drug application (SNDA 20-717 /S-008) Provigil (modafinil) Tablets, Cephalon, Inc., indicated for use to improve wakefulness in patients with excessive sleepiness associated with disorders of sleep and wakefulness.

8:15	Opening Remarks	FDA
	Overview of Issues	
8:45	<u>Sponsor Presentations</u>	Cephalon Incorporated
	<ul style="list-style-type: none">• Introduction• Review of Excessive Sleepiness• Overview of Efficacy and Safety	
9:45	<u>FDA Presentation</u>	
11:15	Questions from Committee to FDA	
12:00	Lunch	
1:00	Open Public Hearing	
2:00	Continuation of Committee Discussion and Response to FDA Questions	
	Break	
5:00	Adjourn	