

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

**Peripheral and Central Nervous System Drugs Advisory Committee**

**September 24, 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

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**Discussions on new drug application (NDA) application 21-487, memantine hydrochloride, Forest Laboratories, Inc., indicated for the treatment of moderate to severe dementia of the Alzheimer's type.**

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8:15	Opening Remarks	FDA
	Overview of Issues	
8:45	<b><u>Sponsor Presentations</u></b>	Forest Laboratories Incorporated
	<ul style="list-style-type: none"><li>• Introduction and Memantine Overview</li><li>• Memantine Pharmacology</li><li>• Efficacy Data</li><li>• Summary and Risk/Benefit</li></ul>	
10:45	<b><u>FDA Presentation</u></b>	
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	