

**FOOD AND DRUG ADMINISTRATION**  
Center for Drug Evaluation and Research (CDER)  
*Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) and the  
Psychopharmacologic Drugs Advisory Committee (PDAC)*  
**AGENDA**  
**July 10, 2008**

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*The committee will discuss the results of FDA's meta-analysis and issues related to antiepileptic drugs and suicidality.*

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8:00 a.m.	Call to Order Introduction of Committee	<b>Larry Goldstein, M.D.</b> Chair, PCNS
	Conflict of Interest Statement	<b>Yvette Waples, PharmD</b> Designated Federal Official
8:15 a.m.	Opening Remarks	<b>Russell Katz, M.D., Director</b> Division of Neurology Products, CDER, FDA
8:30 a.m.	Antiepileptic Drugs and Suicidality: Background	<b>Evelyn Mentari, M.D., M.S., Clinical Safety Reviewer</b> Division of Neurology Products, CDER, FDA
	Antiepileptic Drugs and Suicidality: Statistical Evaluation	<b>Mark Levenson, Ph.D., Statistical Safety Reviewer</b> Quantitative Safety & Pharmacoepidemiology Group, Division of Biometrics 6, CDER, FDA
	Antiepileptic Drugs and Suicidality: Discussion	<b>Evelyn Mentari, M.D., M.S., Clinical Safety Reviewer</b> Division of Neurology Products, CDER, FDA
9:30 a.m.	Questions from the Committee	
10:00 a.m.	<b>Break</b>	
10:15 a.m.	Neurontin/Lyrica: Potentially Suicide Related Adverse Events	<b>Christopher Wohlberg, M.D., Ph.D.</b> Global Medical Team Leader, Lyrica Global Medical Therapeutic Area Lead, Pain Pfizer, Inc.
10:35 a.m.	Lamictal® (lamotrigine): Analysis of Suicidality Data	<b>Jack Modell, M.D.</b> Vice President Clinical Development for Neurosciences GlaxoSmithKline
10:50 a.m.	Preliminary Statistical Comments on Pfizer Gabapentin and Pregabalin Analysis	<b>Mark Levenson, Ph.D., Statistical Safety Reviewer</b> Quantitative Safety & Pharmacoepidemiology Group, Division of Biometrics 6, CDER, FDA
11:05 a.m.	Questions from the Committee	
11:45 a.m.	<b>Lunch</b>	
1:00 p.m.	Open Public Hearing	
3:00 p.m.	<b>Break</b>	
3:15 p.m.	Discussion and questions to the Committee	
5:00 p.m.	<b>Adjourn</b>	