

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

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

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