FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA

On January 7, the committee will discuss new drug application (NDA) 20-427, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of adjunctive therapy for the treatment of refractory complex partial seizures in adults. On January 8, the committee will discuss NDA 22-006, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of treatment of infantile spasms.

Day 1: Wednesday, January 7, 2009

8:00 a.m.	Call to Order and Opening Remarks	**Larry B. Goldstein, M.D.** Acting Chair, Peripheral and Central Nervous System Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D., BCPS** Designated Federal Official
8:15 AM	FDA Introductory Remarks	**Russell Katz, M.D.** Director, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
8:30 AM	**INDUSTRY PRESENTATION**	
10:00 AM	Clarifying Questions	
10:15 AM	**BREAK**	
10:30 AM	**FDA PRESENTATION**	
10:30 AM	Ophthalmic Findings in Adults	**Ronald Farkas, M.D, Ph.D.** Clinical Reviewer, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
11:30 AM	Vigabatrin - Risk Evaluation & Mitigation Strategies (REMS)	**Joyce Weaver, Pharm.D., BCPS** Senior Drug Risk Management Analyst FDA/CDER/Office of Surveillance & Epidemiology
11:45 AM	Clarifying Questions	
12:00 PM	**LUNCH**	

1:00 PM. Open Public Hearing

2:00 PM Questions/Clarifications

3:30 PM **BREAK**

3:45 PM **PANEL DISCUSSION/QUESTIONS**

5:00 PM **ADJOURNMENT**

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AGENDA
-CONTINUED-

Day 2: Thursday, January 8, 2009

8:00 AM	Call to Order	**Larry B. Goldstein, M.D.** Acting Chair, Peripheral and Central Nervous System Drugs Advisory Committee
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D., BCPS** Designated Federal Official
8:15 AM	FDA Introductory Remarks	**Russell Katz, M.D.** Director, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
8:30 AM	**INDUSTRY PRESENTATION**	
10:00 AM	Clarifying Questions	
10:15 AM	**BREAK**	
10:30 AM	**FDA PRESENTATION**	
10:30 AM	FDA Perspective on Effectiveness	**Julia Luan, Ph.D.** Statistics Reviewer, Division of Biometrics CDER, FDA
11:00 AM	Ophthalmic Findings in Pediatrics	**Ronald Farkas, M.D., Ph.D.** Clinical Reviewer, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
11:30 AM	Clinical Studies in Infantile Spasms	**Philip Sheridan, M.D.** Clinical Reviewer, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
12:00 PM	Nonclinical Central Nervous System Pathological Findings	**Larry Schmued, Ph.D** Division of Neurotoxicology, National Center for Toxicological Research, FDA
12:30 PM.	Clarifying Questions	

12:45 PM **LUNCH**

1:30 PM Open Public Hearing

2:30 PM Questions/Clarifications

3:00 PM **BREAK**

3:15 PM Panel Discussion/Questions

5:00 PM **ADJOURNMENT**