

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

Hilton Washington DC/Silver Spring, The Ballrooms
8727 Colesville Road, Silver Spring, MD
MARCH 10, 2011

AGENDA

The committee will discuss, in general, the use of historical-controlled trials for the approval of anticonvulsant monotherapy for seizures of partial origin for antiepileptic drug products that are already approved for adjunctive therapy. The committee will also discuss how this may specifically apply to the approval of the supplemental new drug application (sNDA) 022115/S-006, LAMICTAL XR (lamotrigine extended-release tablets), sponsored by SmithKline Beecham Corporation d/b/a GlaxoSmithKline, for monotherapy in patients 13 years of age and older with partial seizures who are receiving therapy with a single antiepileptic drug (AED).

8:00 a.m.	Call to Order and Opening Remarks	Britt Anderson, M.D., Ph.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 Officer
8:15 a.m.	FDA Introductory Remarks	Russell Katz, M.D. Director, Division of Neurology Products (DNP) Office of Drug Evaluation I (ODE-I) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	GUEST SPEAKER PRESENTATION	
	Historical Control: Withdrawal to Monotherapy	Jacqueline A. French, M.D. Professor, Department of Neurology Director, Clinical Trials Consortium New York University Comprehensive Epilepsy Center
	Historical Control for Epilepsy Conversion to Monotherapy: Methodology	Nancy R. Temkin, Ph.D. Professor, Biostatistics and Neurological Surgery University of Washington
9:30 a.m.	Clarifying Questions	
9:45 a.m.	BREAK	
10:00 a.m.	INDUSTRY PRESENTATION	
	Overview of Epilepsy and Lamotrigine	Thomas Thompson, M.D. Director, Neurosciences Medicine Development Center Physician Project Leader for Lamotrigine GlaxoSmithKline LLC

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AGENDA
– *continued* –

INDUSTRY PRESENTATION (cont.)

Brief Review of the Historical
Control Studies

John Messenheimer, M.D.
Epilepsy Consultant
John Messenheimer, PLLC

LAM30055 – Design, Efficacy,
and Safety Results

John Messenheimer, M.D.

Comparisons Between LAM30055,
US30/31, and the Historical Control
Studies

John Messenheimer, M.D.

Summary and Conclusions

Thomas Thompson, M.D.

Statistical Considerations

Eugene M. Laska, Ph.D.
Research Professor, Biostatistics
New York University Medical Center

11:00 a.m. Clarifying Questions

11:15 a.m. **FDA PRESENTATION**

Lamictal® XR™ (lamotrigine)
Historical Control Trial

Xiang Ling, Ph.D.
Mathematical Statistician
Division of Biostatistics 1, Office of Biostatistics
Office of Translational Science, CDER, FDA

12:15 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. Open Public Hearing

2:30 p.m. Panel Discussion/Questions

3:30 p.m. **BREAK**

3:45 p.m. Panel Discussion/Questions

5:00 p.m. Adjournment