Quick Minutes (Confidential - Not to be Released Outside of the Agency)
Joint Meeting of the Peripheral and Central Nervous System Advisory Committee and the Psychopharmacologic Drugs Advisory Committee
July 10, 2008

The following is an internal report which has not been reviewed of the Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and the Psychopharmacologic Drugs Advisory Committee held on July 10, 2008. A verbatim transcript will be available in approximately two weeks, sent to the Division and posted on the FDA website at http://www.fda.gov/ohrms/dockets/ac/cder08.html#PeripheralCentralNervousSystem.

All external requests for the meeting transcripts should be submitted to the CDER Freedom of Information Office.

The Peripheral and Central Nervous System Drugs Advisory Committee and the Psychopharmacologic Drugs Advisory Committee of the Food and Drug Administration met on July 10, 2008 at the Sheraton Washington North Hotel, Beltsville, Maryland. Larry Goldstein, M.D, chaired the meeting. There were approximately 220 in attendance.

Attendance:

Peripheral and Central Nervous System Advisory Committee Members present (voting):
Larry Goldstein M.D. (Chair); Britt Anderson, M.D., Ph.D. ; Lily K.F. Jung, M.D., M.M.M.; Ying Lu, Ph.D.; Matthew Rizzo, M.D.; Stacy Ann Rudnicki, M.D.

Peripheral and Central Nervous System Advisory Committee Members present (non-voting):
Roy E. Twyman, M.D. (Industry Representative)

Psychopharmacologic Drugs Advisory Committee
(voting)
Jorge Armenteros, M.D.; Rochelle Caplan, M.D.; Gail Griffith, M.D.; Susan K. Schultz, M.D.; Robert F. Woolson, Ph.D.

Psychopharmacologic Drugs Advisory Committee
(non-voting)
William Z. Potter, M.D, Ph.D. (Industry Representative)

Temporary Voting Members
Ruth S. Day, Ph.D.; Sid Gilman, M.D., FRCP; Wayne Goodman, M.D.; Andrew Leon, Ph.D; Richard Malone, M.D.; Daniel S. Pine, M.D.; Delbert G. Robinson, M.D.; Barbara G. Wells, Pharm.D., FCCP, BCPP; Andrew Winokur, M.D., Ph.D.

Drug Safety and Risk Management Advisory Committee Voting Member:
Sean Hennessy, Ph.D

Pediatric Advisory Committee Voting Member:
Melissa Hudsons, M.D.

FDA Participants (non-voting):
Robert Temple, M.D.; Russell Katz, M.D.; Tom Laughren, M.D.; Alice Hughes, M.D.; Evelyn Mentari, M.D., M.S.,; Mark Levenson, Ph.D.

Open Public Hearing Speaker:
Joyce Cramer (President, Epilepsy Therapy Project); Darrel Regier, M.D. (American Psychiatric Association); Andrew G. Finkelstein, P.C. (Finkelstein & Partners, LLP); Andy Briggs (Finkelstein & Partners, LLP); Keith Altman (Finkelstein & Partners, LLP); David Egilman, MD, MPH (Brown University); Jacqueline French, MD (NYU Comprehensive Epilepsy Center); Frank Gilliam, MD, MPH (Director of the Comprehensive Epilepsy Center); Laurence Greenhill, M.D. (New York Psychiatric Institute)

On July 10, 2008, the committee discussed issues related to Anti-epileptic Drugs and suicidality.

Larry Goldstein M.D., (Chair) called the meeting to order at 8:00 a.m. The Committee members and the FDA participants introduced themselves. The conflict of interest statement was read into the record by Yvette Waples, Pharm.D., Designated Federal Official (DFO). The agenda for the meeting was as follows:

8:00	Call to Order Introduction of Committee	**Larry Goldstein, M.D.** Chair, PCNS
	Conflict of Interest Statement	**Yvette Waples, PharmD** Designated Federal Official
8:15 am	Opening Remarks	**Russell Katz, M.D., Director** Division of Neurology Products, CDER, FDA
8:30 am	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 am	Questions from the Committee	
10:00 am	*Break*	

10:15 am	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.
10:35am	Lamictal® (lamotrigine): Analysis of Suicidality Data	**Jack Modell, M.D.** Vice President Clinical Development for Neurosciences GlaxoSmithKline
10:50 am	Preliminary Statistical Comments on Pfizer Gabapentin and Pregabalin Analysis	**Mark Levenson, Ph.D., Statistical Safety Reviewer** Quantitative Safety & Pharmacoepidemiology Group, Division of Biometrics 6, CDER, FDA
11:05 am	Questions from the Committee	
11:45 am	*Lunch*	
1:00 pm	Open Public Hearing	
2:00 pm	*Break*	
2:15pm	Discussion and questions to the Committee	
5:00pm	Adjourn	

Questions to the Committee:

1) Does the Committee agree with the Agency's overall finding of an increase in suicidality for the 11 AEDs analyzed?
(See transcript for complete discussion)
Yes: 20 **No: 0** **Abstain: 1**

2) Does the Committee agree with the Agency's conclusion that the finding of increased suicidality should apply to each of the drugs included in the analyses, despite the observation that the estimate of the Odds Ratio for 3 of the drugs was below 1? If not, to which drugs should the conclusion apply?
(See transcript for complete discussion)
Yes: 18 **No: 3** **Abstain: 0**

3) Does the Committee agree with the Agency's conclusion that the finding should apply to all currently approved chronically administered AEDs, including those not part of the analyses?
(See transcript for complete discussion)
Yes: 15 **No: 5** **Abstain: 1**

4) Does the Committee agree with the Agency's plan to require a Boxed warning for all AEDs?
   If not, does the Committee want to offer guidance on other approaches to communicating this information?
   (See transcript for complete discussion)
   Yes: 4 **No: 14** **Abstain: 3**
   The committee agreed that a Boxed warning should not be included in the product labeling.

5) Does the Committee agree with the Agency's plan to require a Medication Guide?
   If not, does the Committee want to offer guidance on other approaches to communicating this information?
   (See transcript for complete discussion)
   Yes: 17 **No: 4** **Abstain: 0**
   The committee agreed that a Medication Guide should be included in the product labeling. The committee recommended that the Medication Guide be placed on the internet for universal access.

The meeting was adjourned at approximately 5:00 p.m. on July 10, 2008.