FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee Meeting (PDAC)

HILTON WASHINGTON DC/SILVER SPRING
THE MARYLAND BALLROOMS
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

APRIL 8, 2009

AGENDA

The committee will discuss the safety and efficacy of supplemental new drug applications (sNDAs) 22-047/S-010/S-011/S-012,Seroquel XR (quetiapine maleate), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of major depressive disorder and 22-047/S-014/S-015, Seroquel XR (quetiapine maleate), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of generalized anxiety disorder. Particular safety issues for discussion on April 8, 2009, regarding the Seroquel XR applications are concerns regarding exposing a greatly expanded population to a drug with known metabolic side effects and a possible risk of tardive dyskinesia.

8:00 a.m.	Call to Order and Opening Remarks	**Wayne Goodman, M.D.** Acting Chair, PDAC
	Introduction of Committee	
	Conflict of Interest Statement	**Yvette Waples, Pharm.D.** Designated Federal Official
8:10 a.m.	FDA Introductory Remarks	**Thomas Laughren, M.D.** Director, Division of Psychiatry Products (DPP), Office of New Drugs (OND), CDER, FDA

INDUSTRY PRESENTATION

8: 15 a.m.	Introduction and Background on Quetiapine	**Mark Scott, Ph.D.** AstraZeneca
8: 30 a.m.	Efficacy and Short-term Safety in MDD and GAD	**Hans Eriksson, M.D.** AstraZeneca
8: 50 a.m.	Safety Topics of Interest	**Hans Eriksson, M.D.** AstraZeneca
9:25 a.m.	Benefit/Risk Assessment and Risk Management	**Mark Scott, Ph.D.** AstraZeneca
9:35 a.m.	A Clinician's Perspective	**Madhukar Trivedi, M.D.** External Expert

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-CONTINUED-

9:50 a.m.	Concluding Remarks	**Mark Scott, Ph.D.** AstraZeneca
9:55 a.m.	Clarifying Questions	
10:10 a.m.	**BREAK**	

FDA PRESENTATION

10:20 a.m.	Atypical Antipsychotics and the Risk of Sudden Cardiac Death	**Wayne A. Ray, Ph.D.** **Guest Speaker** Department of Preventive Medicine Vanderbilt University School of Medicine
10:40 a.m.	Estimating Sudden Cardiac Death Rates with Death Certificate Data	**Marc B. Stone, M.D.** Senior Medical Reviewer DPP, CDER, FDA
11:00 a.m.	Clarifying Questions	
11:15 a.m.	**LUNCH**	
12:00 p.m.	Open Public Hearing	
1:00 p.m.	Questions/Clarifications	
2:00 p.m.	**BREAK**	
2:10 p.m.	Committee Deliberations	
3:30 p.m.	**ADJOURNMENT**	