FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE
Hilton Hotel, the Maryland Ballroom, Silver Spring, Maryland
8:00 a.m. – 5:00 p.m.
December 13, 2006

AGENDA

The Committee will discuss the results of our ongoing meta-analysis of suicidality data from adult antidepressant trials.

8:00 a.m.	Call to Order and Opening Remarks	Daniel S. Pine, M.D. Acting Chair, Psychopharmacologic Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Cicely C. Reese, Pharm.D. Executive Secretary
8:05 a.m.	FDA Introductory Remarks & Overview of Issues	Thomas P. Laughren, M.D. Director, Division of Psychiatry Products, CDER, FDA
8:20 a.m.	**FDA Presentation**	
	Antidepressants and Suicidality in Adults: Data Overview	Lisa Jones, M.D., M.P.H Medical Reviewer, Division of Psychiatry Products CDER, FDA
8:35 a.m.	Antidepressants and Suicidality in Adults: Statistical Safety Reviewer Evaluation	Mark Levenson, Ph.D. Statistical Safety Reviewer Division of Biometrics 6
9:05a.m.	Antidepressants and Suicidality in Adults: Medical Reviewer Evaluation	Marc Stone, M.D. Senior Medical Reviewer Division of Psychiatry Products
9:35a.m.	Questions	
9:45a.m.	**Break**	
10:00 a.m.	**Open Public Hearing**	
1:30 p.m.	Lunch	
2:15 p.m	Summary and Issues for Committee	Thomas P. Laughren, M.D.
2:30 p.m.	Committee Questions for FDA and Committee Discussion	
3:15 p.m.	**Break**	
5:30 p.m.	**Adjournment**	
