Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the
CDER Psychopharmacologic Drugs Advisory Committee
and the
FDA Pediatric Advisory Committee

September 13-14, 2004

Holiday Inn
8120 Wisconsin Avenue, Bethesda, Maryland

Issue: Discussion of reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder (MDD) and other psychiatric disorders. Preliminary risk data based on the classification of these adverse event reports by the pharmaceutical sponsors of these products were presented at the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held on February 2, 2004. Since that meeting, experts in pediatric suicidality, assembled by Columbia University, have independently classified these reported events, and the FDA has conducted an analysis of these data. The committees will consider the results of FDA's analysis of these independently classified events and will consider what further regulatory action may be needed with regard to the clinical use of these products in pediatric patients. The committees will also consider further research needs to address questions on this topic.

Monday, September 13, 2004

8:00	Call to Order and Opening Remarks	Wayne Goodman, M.D. Chair, Psychopharmacologic Drugs Advisory Committee (PDAC)
	Introduction of Committee	
	Conflict of Interest Statement	LT. Anuja Patel, M.P.H. Executive Secretary, CDER, FDA
8:15	Overview of Issues	Dianne Murphy, M.D. Director, Office of Pediatric Therapeutics, Office of the Commissioner Russell Katz, M.D. Director, Division of Neuropharmacological Drug Products (DNDP), CDER, FDA
8:30	Regulatory History and Background	Thomas Laughren, M.D. Team Leader, DNDP, CDER, FDA
8:45	Recent Observational Studies of Antidepressants (ADs) and Suicidal Behavior	Diane Wysowski, Ph.D. Epidemiologist, Division of Drug Risk Evaluation, Office of Drug Safety (ODS), CDER, FDA
9:00	Brief Report on TADS Trial	John March, M.D., M.P.H. Duke University
9:15	Questions from the Committee	
9:30	Characteristics of Pediatric Antidepressant Trials	Greg Dubitsky, M.D. Medical Officer, DNDP, CDER, FDA
9:40	Classification of Suicidality Events	Kelly Posner, Ph.D. Columbia University
10:05	OCTAP Appraisal of Columbia Classification Methodology	Solomon Iyasu, M.D., M.P.H. Team Leader, Office of Counter-Terrorism and Pediatric Drug Development (OCTAP), CDER, FDA

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Monday, September 13, 2004, Agenda Continued

10:15	Questions from the Committee	
10:30	**Break**	
10:45	Results of the Analysis of Suicidality in Pediatric Trials of Newer Antidepressants	Tarek Hammad, M.D., Ph.D., M.Sc., M.S. Senior Medical Reviewer, DNDP, CDER, FDA
11:30	Comparison Between Original ODS and Current DNDP Analyses of Pediatric Suicidality Data Sets	Andrew Mosholder. M.D., M.P.H. Epidemiologist, Division of Drug Risk Evaluation, ODS, CDER, FDA
11:45	Questions from the Committee	
12:00	**Lunch**	
1:00	Sponsor Presentations	
	Citalopram and Escitalopram Pediatric Safety Data	Jeffrey Jonas, M.D. Vice President, CNS, Forest Laboratories, Inc.
	Sertraline Use in Pediatric Population: A Risk Benefit Discussion	Charlotte Kremer, M.D. Therapeutic Head, Psychiatry, WWM, Medical and Development Sciences, Pfizer, Inc.
	Title to be Announced	Joseph S. Camardo, M.D. Senior Vice President, Global Medical Affairs, Wyeth Pharmaceuticals
2:00	Open Public Hearing	
3:30	**Break**	
3:45	Open Public Hearing	
6:00	Summary by Committee Chair	
6:15	Adjourn	

Tuesday, September 14, 2004

8:00	Call to Order and Opening Remarks	Wayne Goodman, M.D. Chair, PDAC
8:15	Opening Comments	Thomas Laughren, M.D. Team Leader, DNDP, CDER, FDA
8:30	Committee Discussion	
	Summary Comments	Wayne Goodman, M.D. Chair, PDAC
	Adjourn	