Food and Drug Administration
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

DRAFT AGENDA

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.

September 13, 2004

FDA Presentations

Sponsor Presentations

Open Public Hearing

Chair's Summary

Adjourn

September 14, 2004

Committee Discussion

Adjourn