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

Questions and Issues

Occurrence of Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients

Questions/Issues for which FDA would like committee discussion and feedback:

1. Please comment on our approach to classification of the possible cases of suicidality (suicidal thinking and/or behaviors) and our analyses of the resulting data from the 23 + 1 pediatric trials involving 9 antidepressant drugs.

2. Do the suicidality data from these trials support the conclusion that any or all of these drugs increase the risk of suicidality in pediatric patients?

3. If the answer to the previous question is yes, to which of these 9 drugs does this increased risk of suicidality apply?
   - Please discuss, for example, whether the increased risk applies to all antidepressants, only certain classes of antidepressants, or only certain antidepressants.

4. If there is a class suicidality risk, or a suicidality risk that is limited to certain drugs in this class, how should this information be reflected in the labeling of each of the products?
   - What, if any, additional regulatory actions should the Agency take?

5. Please discuss what additional research is needed to further delineate the risks and benefits of these drugs in pediatric patients with psychiatric illness.