

*Draft*  
**Pediatric Advisory Committee Meeting**  
**March 22, 2006**  
**Questions for the Committee**

Because these products have been shown to be effective when used to treat children who have been properly diagnosed as having ADHD, there will continue to be a need for access to these therapies. You have received information on potential cardiovascular and neuropsychiatric risks associated with the use of medications to treat ADHD in children. This information included adverse events from spontaneous reports and clinical trial data, the current labeling and FDA's plans for additional studies on cardiovascular risk.

In consideration of this information, please address the following questions concerning psychiatric and cardiovascular adverse events.

**Psychiatric Adverse Events potentially associated with drugs to treat ADHD in children:**

1. What are the important messages you think should be conveyed to physicians and parents regarding these potential risks? In your discussion, please comment on the strength of the evidence relevant to the identified risks. As appropriate, identify differences among drug products.
2. Are the messages about these potential risks being adequately communicated through current labeling?
3. If not, what additional information or changes should be made to the label?
4. What other mechanisms should be employed to communicate these potential risks to practitioners, families and patients?

**Cardiovascular Adverse Events potentially associated with drugs to treat ADHD in children:**

5. What are the important messages you think should be conveyed to physicians and parents regarding these potential risks? In your discussion, please comment on the strength of the evidence relevant to the identified risks. As appropriate, identify differences among drug products.
6. Are the messages about these potential risks being adequately communicated through current labeling?
7. If not, what additional information or changes should be made to the label?
8. What other mechanisms should be employed to communicate these potential risks to practitioners, families and patients?