Subsequent to the published announcement in the 10 March 2006 Federal Register regarding amendment of the Pediatric Advisory Committee meeting agenda, Lilly is providing an addendum to our briefing document submitted to FDA on 06 March 2006.

This addendum contains the following supplementary attachments relevant to the review and discussion of cardiovascular events at this advisory committee meeting.

**Post-marketing Adverse Events**
7) Limitations in Determining Spontaneous Adverse Event Reporting Rates and Comparing Atomoxetine to other ADHD Medications.

**Integrated Analysis of the Atomoxetine Cardiovascular Effect**

**Evaluation of the Stimulant and Potential Abuse Liability of Atomoxetine**
9) Atomoxetine Increases Extracellular Levels of Norepinephrine and Dopamine in Prefrontal Cortex of Rat: A Potential Mechanism for Efficacy in Attention Deficit/Hyperactivity Disorder, manuscript published 2002 (Bymaster, FP et al. Atomoxetine increases extracellular levels of norepinephrine and dopamine in prefrontal cortex of rat: a potential mechanism for efficacy in attention deficit/hyperactivity disorder. *Neuropsychopharmacology* 2002; 27(5):699-711).


Lilly hopes that the committee will find the enclosed information useful as they consider all available evidence related to the important safety deliberations by the FDA and committee members. Clearly benefit and risks have to be assessed collectively. Lilly
looks forward to providing further comment on these and other matters during the Advisory Committee hearing on March 22, 2006.