

**MEMORANDUM      DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION**

**DATE:**            March 28, 2007

**FROM:**            Dianne Murphy, MD  
Director, Office of Pediatric Therapeutics  
Office of the Commissioner

**SUBJECT:**        Overview of the April 11<sup>th</sup>, 2007 Meeting of the Pediatric Advisory Committee (PAC)

**TO:**                Members of the Pediatric Advisory Committee

Thank you for agreeing to participate in the upcoming Pediatric Advisory Committee (PAC) meeting on the 11<sup>th</sup> of April. Attached you will find background information and an overview of the agenda for the meeting on the 11<sup>th</sup>.

At 4 p.m., the PAC will officially convene in an open session to discuss adverse event reports for drugs granted pediatric exclusivity as mandated by Section 17 of the Best Pharmaceuticals for Children Act (BPCA), namely, fluvastatin (Lescol<sup>®</sup>) and octreotide (Sandostatin<sup>®</sup>). The committee will also receive updates to adverse event reports for orlistat (Xenical<sup>®</sup>) and oxybutynin (Ditropan<sup>®</sup>) which were requested by the PAC when the reports were first presented. Oxybutynin received an abbreviated presentation at the November 16, 2006 meeting. It has since come to our attention that this product probably warranted a standard presentation which includes an assessment of all pediatric adverse events since approval. Thus, you will receive the clinical and Office of Safety and Epidemiology reviews for both this meeting and the November 16<sup>th</sup>, 2006 meeting for oxybutynin.

The background package for the adverse event reviews of the April 11<sup>th</sup> meeting includes the following documents as paper copies and saved under separate folders onto CD for each drug in addition to this cover memo:

- 1-year Post-Pediatric Exclusivity Post-marketing Adverse Events
- 1-year Post-Pediatric Exclusivity Drug Use Reviews
- The Medical and Clinical Pharmacology reviews of trials conducted for pediatric exclusivity
- Product labeling for drugs to be presented during the adverse event reporting portion of the meeting (please note that there is an indication in the margin of each label that identifies the pediatric sections of the product label)

The FDA relies heavily on the knowledge, judgment, experience, and wisdom of the members of its advisory committees to provide us with feedback and advice on how best to promote and protect the public health of the United States. We thank you for your time and effort, and we look forward to seeing you and hearing from you on April 11<sup>th</sup>, 2007.