

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

DATE: March 19, 2007

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

SUBJECT: Overview of the April 11th & 12th, 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 11th of April and the combined PAC and Anti-Infective Drugs Advisory Committee (AIDAC) meeting on April 12th. We also wish to thank you for your willingness to participate in the training on April 11th. Attached you will find background information and an overview of the agenda for the meetings and the training session on the 11th. We have a rather unusual arrangement of meetings and training as outlined below.

On April 11th, the AIDAC is having a closed session to discuss trial design issues which are considered trade secret and/ or commercial and confidential. This session involves products being studied for a common pediatric condition and a number of the PAC members will be augmenting the AIDAC. We encourage those of you who are members of the PAC but who are not officially participating in this part of the program to attend the morning session as listeners. The PAC is occasionally asked to provide advice on pediatric trials and we think this would be a useful discussion from a learning perspective.

For those not officially invited to participate in the AIDAC closed session, the official training component for the PAC will be held from noon until 4 p.m. at another location within the building. We highly recommend you attend this session, as it will focus on adverse event databases from across the agency and discuss their differences. In addition, we will hear from internal experts on the labeling process and risk communication.

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) for fluvastatin (Lescol[®]) and octreotide (Sandostatin[®]). The committee will also receive updates to adverse event reports for orlistat (Xenical[®]) and oxybutynin (Ditropan[®]) 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 16th, 2006 meeting for oxybutynin.

The morning of April 12th, the AIDAC and PAC will meet to discuss scientific issues surrounding the development of therapies for Shiga toxins 1 and 2 for the treatment of Shiga toxin-producing bacterial infections.

The background package for the adverse event review portion of the April 11th 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)

In addition to the above materials, you will be receiving information under separate mailing for the combined meeting on Shiga toxin on the 12th.

We will provide you copies of the slides from the training presentations at the session.

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 11th & 12th, 2007.