June 27, 2006
Pediatric Subcommittee of the ODAC
Questions

Session I: BPCA & Oncology Experience

1. Over the past 10 years, when exclusivity incentives have been available for development of pediatric therapeutics, there has been a number of oncology products studied. This has generated useful and important information for pediatric oncology patients. However, much work remains to be done.
   - Please discuss the limitations, strengths, and weaknesses of the approaches and efforts thus far.
   - Please discuss ways in which FDA can improve the process. In your response, please consider issues such as the timing of pediatric studies, types of studies to ask for in the WR, how best to incorporate pre-clinical data.