June 27, 2007
Pediatric Subcommittee of the ODAC
Questions

Session II: 13-*cis*-retinoic acid Clinical Experience

1. Given the results of the Phase 3 RCT in high risk neuroblastoma patients who received intensive chemotherapy, radiotherapy, autologous stem cell transplant and 13-*cis*-retinoic acid, should the FDA ask [in a WR] for submission of these data to FDA as a sNDA [i.e., to potentially support a new indication]?

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2. Please discuss other types of studies/data that should be part of a WR to further inform the safety, dosing, and efficacy of 13-*cis*-retinoic acid in pediatric patients with high risk neuroblastoma.