Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee
October 9, 2003

Background Documents

AM Session

TAB 1 Best Pharmaceuticals for Children Act, 2002. Sections 2 and 3 only for this discussion. http://www.fda.gov/cder/pediatric/PL107-109.pdf

TAB 2 Reference Articles

- Frost, B-M. **Pharmacokinetics of Doxorubicin in Children With Acute Lymphoblastic Leukemia: Multi-Institutional Collaborative Study**. Med Pediatr Oncol. 2002; 38:329-337.
- Groninger, E, et al. **Pharmacokinetics of Vincristine Monotherapy in Childhood Acute Lymphoblastic Leukemia**. Ped Rsch. 2002;2(1):113-118.
- Hempel, G, et.al. **Peak plasma concentrations of doxorubicin in children with acute lymphoblastic leukemia or non-Hodgkin lymphoma**. Canc Chemother and Pharm. 2001
- Nath, CE. **Population pharmacokinetics of amphotericin B in children with malignant diseases**. J Clin Pharmacol. 2001; 52:671-680.

TAB 3 List of Off-patent Oncology Drugs with abbreviated labeling (i.e., Indications section, Dosing and Administration section, and any sections containing pediatric information)

TAB 4 Approved Oncology Drugs with Pediatric Labeling, including abbreviated labeling (i.e., Indications section, Dosing and Administration section, and any sections containing pediatric information)

TAB 5 Anderson, B. Meeting Summary: NCI/CTEP Workshop – Cancer Pharmacology In Infants And Young Children. May 9, 2003.

PM Session

TAB 1 Pawar, S. and Kumar, A. **Issues in the Formulation of Drugs for Oral Use in Children – Role of Excipients**. Pediatr Drugs. 2002; 4(6):371-379.

TAB 2 Nahata, MC. **Pediatric Drug Formulations: Challenges and Potential Solutions**. Annals of Pharmacother. Feb 1999; 33:247-249.

TAB 3 Kovarik, JM, et.al. **Clinical Development of an Everolimus Pediatric Formulation: Relative Bioavailability, Food Effect, and Steady-State Pharmacokinetics**. J Clin Pharmacol. 2003;43:141-147.

TAB 4 Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations. March 2003. http://www.fda.gov/cder/guidance/5356fnl.pdf

TAB 5 Guidance for Industry: Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications. April 2003. http://www.fda.gov/cder/guidance/5341fnl.pdf