

Previous Meetings of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)

1.	Mar 17, 2004	Agenda: The subcommittee will discuss the following topics: (1) Safety monitoring in clinical studies enrolling children with cancer, and (2) the use of nonclinical data to supplement clinical data for evaluation of cancer therapies.
2.	Oct 9, 2003	(1) Consider off-patent oncology drugs for which pediatric studies are needed and discuss the availability of information concerning the safe and effective use of the drugs in the pediatric population, whether additional information is needed, and whether new pediatric studies concerning the drugs may produce health benefits in the pediatric population, as mandated by the Best Pharmaceuticals for Children Act (BPCA), and (2) discuss age-appropriate formulation changes to facilitate dosing of products used in the pediatric oncology setting.
3.	Jul 15, 2003	(1) Pharmacogenetic testing for thiopurine methyltransferase deficiency in patients for whom treatment with 6-mercaptopurine is being considered; and (2) overcoming challenges in pediatric oncology product development: regulatory oversight of multinational clinical studies.
4.	Mar 4, 2003	discuss pediatric labeling for oncology products.
5.	Oct 17, 2002	discuss the timing of the initiation of pediatric oncology clinical studies in a drug development program. The input from this meeting will be used in developing FDA policy to the application of the pediatric rule and the issuance of written requests under the Best Pharmaceuticals for Children Act.
6.	Nov 28, 2001	discuss the implementation of the pediatric rule with regard to study designs, ethical and developmental considerations, and extrapolation of findings from adult to pediatric cancer patients.
7.	Jun 28, 2001	The purpose of this meeting is to provide advice to the FDA on when pediatric solid tumors and CNS malignancies may be considered to be the same indication as adult malignancies. (Pediatric Subcommittee).
8.	Apr 24, 2001	The Pediatric Oncology Subcommittee will discuss parameters used for extrapolation from adult to the pediatric setting in the hematological malignancies of leukemia and lymphoma. (Pediatric Subcommittee). Discussion of single patient use of non-approved oncology drugs and biologics. This is a continuation of the discussion started at the December 13 and 14, 2000 meeting. (Pediatric Subcommittee).
9.	Sep 12, 2000	Topic: The subcommittee will discuss parameters used in oncology for extrapolation from the adult to the pediatric setting. (Pediatric Subcommittee of the Oncologic Drugs Advisory Committee). Topic: The subcommittee will discuss parameters used in oncology for extrapolation from the adult to the pediatric setting. (Joint meeting of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee).