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

Questions to Subcommittee

Morning Session

Off-patent oncology drugs for which pediatric studies are needed: 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)

The BPCA of 2002 provides a mechanism to study off-patent medications in pediatric populations.

1. What factors should be considered in selecting off-patent drugs for study in children with cancer (these may include use in only a pediatric population, use in particular diseases, use in particular age groups, or toxicity questions of particular concern)?

2. Are there any comments, on the proposed selections as discussed by the National Cancer Institute, on the drugs actinomycin-D and vincristine as priority choices, and others to follow?

3. Are there any other off-patent oncology drugs that should be studied in children with cancer that you would suggest? Please indicate the rationale.

Afternoon Session

Age-appropriate formulation changes to facilitate dosing of products used in the pediatric oncology setting

1. What factors would be considered essential in the development of a formulation for children with cancer? Please comment on any age-, disease-, or pharmaceutical-specific considerations.

2. What type of testing or clinical trial design would you recommend for establishing the efficacy and safety of a new formulation for an existing oncology drug that already has efficacy and safety demonstrated in the same population?

3. What type of testing or clinical trial design would you recommend for establishing the efficacy and safety of a new formulation for an existing oncology drug that already has efficacy and safety demonstrated in a different population?