

PEDIATRIC ONCOLOGY SUBCOMMITTEE  
ANNOTATED READING LIST FOR MARCH 4<sup>TH</sup> MEETING

1. 1977 Pediatric Use Guidance- *reflection of FDA thinking 25 years ago with a focus on safety and metabolic differences among various age groups*
2. 1996 The Content and Format for Pediatric Use Supplements- *Guidance on submitting data for pediatric use to the FDA*
3. 1998 Providing Clinical Evidence for Effectiveness for Human Drug and Biological Products- *General guidance on principles and trial design considerations for clinical evidence*
4. 1998 General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products-*Comments on definitions and study designs*
5. 1998 Pediatric Rule- *The Introduction provides a rationale for the inclusion of pediatric data in those circumstances when the Rule would be triggered and compares the Rule to the incentive program*
6. 2000 Guidance on the Pediatric Rule- *Guidance on the requirements and procedures of the 1998 Pediatric Rule with comment on the interaction between the Rule and Pediatric Exclusivity*
7. 2000 International Conference on Harmonization E-11 Document-Clinical Investigation of Medicinal Products in the Pediatric Population- *Consensus document containing principles and definitions*
8. Code of Federal Regulations Title 21 Chapter 1 Part 201 Sections 201.56 and 201.57 General and specific requirements on content and format of labeling for human prescription drugs
9. 2001 Guidance on Clinical Studies Section of Labeling for Prescription Drugs and Biologics- Content and Format- *General comments on the clinical information in product labeling*
10. 2001 Guidance on Format and Content of Clinical Pharmacology Section of Human Prescription Drug Labeling- *General comments on the pharmacology information in product labeling*
11. 2002 Best Pharmaceuticals for Children Act- *Within the Act are specific sections dedicated to the dissemination of information about the results of pediatric studies*