Questions to the Committee for April 2003 CPSC Meeting
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Topic #1 Quantitative risk analysis using exposure-response for determining dose adjustment for special populations

Standardized Approach

- What treatment circumstances (e.g.: intrinsic/extrinsic factors or therapeutic areas) this standardized approach will not be applicable?
- Do exposure-response frequently differ between special and typical populations? If so, how can the differences be detected?

Population PK/PD

- Is the population approach robust and generalizable for analyzing exposure-response data in efficacy and safety studies with sparse PK sampling?
- What are the important study design and drug-specific factors to be considered when applying such approach? What are the limitations?

Utility Function

- Can the presented approach be generalized to other scenarios?

Topic # 2 Pediatric population pharmacokinetics study design template and analyses of the FDA pediatric database

- Are the proposed objectives for pediatrics PPK studies reasonable?
- Is the proposed pediatrics PPK study design template reasonable?

Topic # 3 Pharmacogenetics: improvement of existing drug treatments

- What data and information about pharmacogenetics should be included in prescription drug labels in order to assure that they are scientifically accurate, readable and useful to prescribers, patients and others? "Useful", in this context, refers to the type of pharmacogenetic data or information, the level of detail, and its placement in the appropriate sections of the label.

- How should pharmacogenetic terms, in the absence of clear or internationally agreed upon definitions, be handled in drug labels to assure consistency across different drugs, and to avoid confusion?

Topic # 4 Drug interactions: metabolism and transport-based

- What are the advantages and limitations of the classification system proposed for metabolic drug interaction? and how can the system improve drug product labels ?
- In view of the high likelihood that a patient may be taking multiple drugs at any given time, to what degree would the system help or compromise the ability to identify drug interactions?
- If an NME is classified as a potent inhibitor or a sensitive substrate, what other factors need to be considered, if it has no unique therapeutic advantage over existing treatments for the indication?