

# Questions for Pediatric Advisory Committee

Feb 14, 2005

## Question 1

- OPT proposes to submit an abbreviated summary report to the PAC for drugs where the 1-year safety review does not raise a safety concern, i.e., there were no post-marketing reports submitted or the reported pediatric events did not provide any concern of a possible safety risk.
- The entire written summary will not be presented at a public PAC meeting. However, a slide summarizing the product review and our recommendation will be presented.
- Do you concur with this approach?

## Question 2

- **OPT proposes to provide a public presentation of the mandated safety review at the PAC meeting for drugs where the 1-year safety review raised a possible pediatric safety signal, i.e., increase in the frequency or severity of expected adverse events relative to adults or background rate; occurrence of unexpected or new serious pediatric events; reports of events that are unique to pediatric patients.**
- **When possible, in addition to the adverse event reporting, the presentation will include an assessment of incidence rates, biologic plausibility and review of the literature.**
- **Do you concur with this approach?**

## Question 3

- **The limitations of spontaneous post-marketing adverse event reporting system are well known to you. Please discuss and prioritize potential programs, assuming additional resources were available, to supplement and/or overcome the limitations of spontaneous reporting system for assessing and monitoring safety of marketed drug products in the pediatric population.**

## Question 3 (cont'd)

- **Some examples of potential programs include**
  - **Population-based active surveillance**
  - **Analysis of claims databases e.g. UnitedHealth, Harvard Pilgrim, TenCare**
  - **Exposure and /or outcome/disease registries and creation of linkages with AERS**
  - **Long-term pediatric safety studies to assess drug adverse events including assessment of growth and development:**
    - **Discuss if and how prioritization of products for additional long term studies might be approached.**