Pediatric Advisory Subcommittee Meeting Open Meeting February 3 & 4, 2004

Draft Questions

- 1. Given the differences in cardiac disease processes that occur in adults and children, in what cases (if any) can adult data from approved imaging drugs be extrapolated to pediatric patients in whom cardiac imaging is needed? If so, in what cardiac disease states?
- 2. Assuming further studies in pediatric patients are needed, we would like you to further define the gaps in our knowledge regarding imaging agents to be evaluated for cardiac imaging applications.

Please discuss each of the following questions for each imaging modality (cardiac CT, cardiac MRI, cardiac US, and cardiac nuclear imaging)

- a) What imaging agents need further study?
- b) What populations should be studied?
- c) What disease states should be studied?
- d) What endpoints should be used?
- e) How should a trial be designed?
- f) How should the standard for comparison be defined? Is there a gold-standard?
- 3. Are there new developments in the field of adult cardiac imaging that may have potential application to the pediatric population? Can we anticipate the need for future drug development for pediatric cardiac imaging?