EAR, NOSE AND THROAT DEVICES PANEL MEETING
AUGUST 16, 2002

QUESTIONS FOR PANEL DISCUSSION

1. What is the role of animal studies in the development of an IMEHD? When should preclinical animal studies be performed to support the safety and performance of an IMEHD?

2. What additional assessments, if any, would you recommend be included in Section 5 (Investigational Device Exemptions) to evaluate the safety and effectiveness of the IMEHD?

   a) Currently there are several hearing aid fitting algorithms for conventional hearing aids, based on real-ear measurement techniques. These algorithms predict appropriate gain as a function of frequency for various patterns/magnitudes of hearing loss and hearing aid circuitry (e.g., linear vs. compression).

      (i) Should IMEHD manufacturers be responsible for developing similar fitting algorithms for their devices?

      (ii) If so, should there be common units of measurement among different manufacturers?

   b) What control condition(s) should studies with an IMEHD include? Should it be "state-of-the-art" acoustic hearing aids? If so, how does one define "state-of-the-art" or "optimally fit" if they are to be utilized in the controls? Should the condition include a comparison to the “best aided” condition, including binaural amplification?

   c) Previous clinical studies with the two approved IMEHDs showed enhanced patient satisfaction with these devices despite the fact that objective hearing assessment results were similar to those using conventional hearing aids. What additional assessments, if any, could be used to demonstrate an enhancement in hearing performance to account for a subjective improvement in patient satisfaction?

3. Conventional hearing aid labeling includes performance characteristics based on standardized measurement methodology (i.e., ANSI S3.22, 1996). Given the different types of implantable middle-ear hearing devices (e.g., semi- vs. totally-implantable; electromagnetic vs. piezoelectric), what, if any performance characteristics can be shared among these different device types? What performance characteristics would you want to standardize and include in device labeling (APPENDIX B) common to all IMEHD devices?