

## Questions for Panel Discussion

1. The risks to health presented include Irritation, Infection, and Contamination. Have all the risks to health been identified? If not, what additional risks should be described?
2. The device characteristics identified to address potential risks include:
  - Non- toxic / non-irritating addressed by biocompatibility testing,
  - Infection addressed by sterile packaging with anti-microbial chemical preservative or sterile unit dose package,
  - Stability of formulation over labeled shelf life,
  - Appropriate labeling and tamper resistant packaging.Are there additional features that should be considered to address potential risks?
3. Are clinical data needed to evaluate these devices, or is pre-clinical toxicology, microbiology and labeling sufficient to assess safety and effectiveness?
4. Are the pre-clinical, clinical and labeling items identified in the May 1, 1997 Guidance for Industry, Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products sufficient to serve as the special controls necessary to address the concerns and risks associated with this lubricating/cleaning device for artificial eyes?