

P010019

QUESTIONS FOR PANEL DISCUSSION

- 1. Do the data presented in PMA P010019 provide reasonable assurance of safety and effectiveness for the proposed indications for use?**
- 2. Does the panel recommend any modification of the proposed wording of the indication statement?**
- 3. Please discuss the merits of including the maximum 30 day time period in the indication statement. Does the panel recommend that it be included in only other sections of the product labeling rather than the indication section?**
- 4. Does the panel have any specific recommendations for the proposed product labeling in terms of warnings, precautions, clinical data outcomes or practitioner directed or patient directed labeling?**
- 5. Does the panel recommend that the sponsor conduct a prospective post-approval study within the U.S. population to gather information on the incidence of microbial keratitis?**
- 6. In consideration of potential differences in the standard of care and device usage patterns outside of the U.S., does the panel have any recommendation concerning the use of foreign data in the post approval study?**