

**OPHTHALMIC DEVICES PANEL MEETING  
MAY 23, 2003**

**PMA P030002  
QUESTIONS FOR PANEL DISCUSSION**

1. This is the first IOL that proposes accommodation as its mechanism of action.
  - a). Do the effectiveness data support a claim of accommodation?
  - b). What performance issues should be considered both generally and for product labeling?
2. Do you believe that the sponsor has demonstrated the stability of the hinge, and therefore the stability of the accommodative refractive effect?
3. Does the panel recommend any other modifications to the proposed:
  - a). Physician labeling?
  - b). Patient labeling?
4. Do the data in PMA P030002 support the proposed indication statement?
  - ?? Primary implantation for the visual correction of aphakia in adult patients with cataracts.
  - ?? Provide improved near, intermediate, and distance vision without spectacles.