

OPHTHALMIC DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE  
One Hundred and Tenth Meeting

April 25, 2008

OPEN SESSION

AGENDA\*

Panel Chairperson (Acting)  
Jayne S. Weiss, M.D.

Executive Secretary  
Karen F. Warburton, M.H.S.

8:30 AM Call to Order  
Conflict of Interest Statement  
Introductory Remarks

Laser-assisted in situ keratomileusis (LASIK) Post Market Experience

8:45 AM Open Public Hearing\*\*

10:00 AM Break

10:15 AM Open Public Hearing\*\*

11:30 PM Lunch

12:30 PM FDA Presentation

- Introduction
- LASIK Regulatory Background
- ANSI Refractive Laser Standard
- FDA Postmarket Assessment
- Quality of Life Assessment
- Adverse Event Reporting

2:00 PM Panel Questions for FDA

2:15 PM Guest Speaker and Panel Questions

2:30 PM FDA Questions and Panel Discussion

3:30 PM Break

## Phakic Intraocular Lens (PIOL) Post Market Experience

- 3:45 PM Open Public Hearing\*\*
- 4:00 PM FDA Presentation
- PIOL Regulatory Background
  - ANSI/ISO PIOL Standard
- 4:15 PM FDA Questions and Panel Discussion
- 5:00 PM Adjourn

\*All times are approximate.

\*\*Open Public Hearings – Interested persons may present data, information or views, orally or in writing, on the meeting agenda. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Weiss will recognize unscheduled speakers as time allows. Only the Panel may question speakers during the open public hearings.

DRAFT