

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

June 10, 2008

Panel Chairperson (Acting)
Neil M. Bressler, M.D.

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

AGENDA*

- 8:00 AM Call to Order
Conflict of Interest Statement
Introductory Remarks
- 8:15 AM FDA Award Presentation and Updates
- Recognition given to William D. Mathers, M.D. for past service as
Panel Chair
- Malvina B. Eydelman, M.D., Director
Division of Ophthalmic and Ear, Nose and Throat Devices
- Kesia Y. Alexander, Ph.D.
Chief, Intraocular and Corneal Implants Branch
- Kwame O. Ulmer, M.S.
Chief, Diagnostic and Surgical Devices Branch
- Quynh T. Hoang, M.S.
Acting Chief, Vitreoretinal and Extraocular Devices Branch
- Danica Marinac-Dabic, M.D., Ph.D.
Chief, Epidemiology Branch
Office of Surveillance and Biometrics
Post Approval Study Program Update
- 9:00 AM Open Public Hearing**
- 10:30 AM Break
- 10:45 AM Open Public Hearing**
- 11:45 AM Lunch

12:45	PM	<p>FDA and CDC Guest Speaker Presentations</p> <p>James F. Saviola, O.D. – Introduction</p> <p>Gene Hilmantel, OD, MS – <i>Fusarium</i> Keratitis Outbreak Update</p> <p>Jennifer Rabke Verani, MD, MPH, CDC Guest Speaker Multistate Outbreak of <i>Acanthamoeba</i> Keratitis Associated with Use of a Contact Lens Solution</p> <p>Bernard P. Lepri, OD, MS, MEd – What Do We Know About Contact Lens Wearers</p> <p>Carol Clayton – Patient Labeling for Contact Lenses and Care Products</p> <p>Joseph C. Hutter, PhD – Lens and Solution Physical and Chemical Interactions</p> <p>Myra Smith, MS – Microbiology Issues</p> <p>Govinda S. Visvesvara, PhD, CDC Guest speaker Resistance of <i>Acanthamoeba</i> Cysts to Disinfecting in Multiple Contact Lens Solutions</p> <p>Molly Ghosh, PhD, DABT – Lens – Solution Interactions: Impact on Biocompatibility</p> <p>Marc Robboy, OD – The Impact of Si-Hy CLs on Clinical Testing Methodology</p>
3:00	PM	Break
3:15	PM	Panel Discussion and FDA Questions
4:30	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. Bressler will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearings.