

OPHTHALMIC DEVICES PANEL

One Hundred and Fourth Meeting

OPEN SESSION

AUGUST 2, 2002

8:30 A.M. - 3:00 P.M.

8:30 - 8:40 Call to Order Jayne S. Weiss, M.D. - Chair

Introductory Remarks Conflict of Interest Statement
Sara M. Thornton - Executive Secretary

8:40 - 9:10 **OPEN PUBLIC HEARING SESSION**

9:10 **OPEN COMMITTEE SESSION**

Jayne S. Weiss, M.D., Chair

GENERAL ISSUES DISCUSSION

Presented by: Intraocular and Corneal Implants Branch
Donna R. Lochner, Branch Chief

Topic: Discussion of design elements for clinical studies of phakic intraocular lenses (IOLs)

The panel's recommendations will be used to further develop FDA's guidance document for phakic IOLs and refractive implants.

The panel's suggestions will be taken into consideration by the American National Standards Institute (ANSI) and International Standards Organization (ISO) Phakic IOL Standards development committees

9:10 - 9:15 **FDA PRESENTATION**

GUEST SPEAKER PRESENTATIONS

9:15 - 9:45 **Emory University Group**
Specular microscopy (endothelial cell counts)

Henry F. Edelhauser, Ph.D.

Bernard E. McCarey, Ph.D.

9:45 - 10:05 Panel Questions for the Speakers

10:15 - 10:35

Storm Eye Institute Group
Lens opacity

Liliana Werner, M.D., Ph.D.

10:35 - 10:55

Panel Questions for the Speakers

10:55 - 11:25

OPEN PUBLIC HEARING SESSION

11:25 - 12:25

LUNCH

12:25 - 2:00 p.m.

PANEL DELIBERATIONS

QUESTIONS FOR PANEL DISCUSSION

Discussion Leader, Question 1. - Michael R. Grimmett, M.D.

Discussion Leader, Question 2. - William D. Mathers, M.D.

Discussion Leader, Question 3. - Mark A. Bullimore, MCOptom, Ph.D.

2:00 - 3:00

Panel Discussion on Remaining Issues

3:00

OPEN MEETING ADJOURNED

NOTE: 15-MIN. BREAKS MAY BE GIVEN AT AN APPROPRIATE TIME DURING THE PROCEEDINGS