

OPHTHALMIC DEVICES PANEL

One Hundred and Fifth Meeting

Gaithersburg Marriott, Salons A, B & C
9751 Washingtonian Blvd.
Gaithersburg, MD

OPEN SESSION

MAY 23, 2003

8:30 A.M. – 3:30 P.M.

8:30 Call to Order Jayne S. Weiss, M.D. - Chair
Introductory Remarks Sara M. Thornton - Executive Secretary
Conflict of Interest Statement
Appointment to Temporary Voting Status

8:45 - 9:15 **OPEN PUBLIC HEARING**

OPEN COMMITTEE SESSION

Jayne S. Weiss, M.D., Chair

9:15 - 9:30

DIVISION UPDATE

A. Ralph Rosenthal, M.D., Director
Division of Ophthalmic and Ear, Nose and Throat Devices

BRANCH UPDATES

James F. Saviola, O.D.
Chief, Vitreoretinal and Extraocular Devices Branch
Jan C. Callaway
Acting Chief, Diagnostic and Surgical Devices Branch
Donna R. Lochner
Chief, Intraocular and Corneal Implants Branch

PMA P030002

9:30 - 10:30

SPONSOR PRESENTATION

CrystaLens™ Model AT-45
Multipiece Silicone Posterior Chamber Accommodating Intraocular Lens

10:30 - 11:00 Panel Questions for the Sponsor

11:00 - 11:20 **FDA PRESENTATION**
Donna R. Lochner – Introduction
Don Calogero– Team Leader
Bernard L. Lepri, O.D., M.S., M.Ed. – Clinical Reviewer

11:20 - 11:30 Panel Questions for FDA

11:30 - 11:35 Additional Comments from the Sponsor

11:35 - 12:35 **LUNCH**

12:35 - 3:30 p.m. **COMMITTEE DELIBERATIONS**

Primary Panel Reviewers:

Anne L. Coleman, M.D., Ph.D.
Arthur Bradley, Ph.D.

PANEL DISCUSSION OF P030002
to include FDA questions to the Panel

30-MINUTE OPEN PUBLIC HEARING SESSION

FDA – CLOSING COMMENTS (5 minutes)

SPONSOR – CLOSING COMMENTS (5 minutes)

Voting Options Read

PANEL RECOMMENDATION TAKEN BY VOTE

POLLING OF PANEL VOTES

COMMENTS FROM CONSUMER AND INDUSTRY REPRESENTATIVES

FINAL PANEL COMMENTS

3:30 p.m. OPEN MEETING ADJOURNED

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