

OPHTHALMIC DEVICES PANEL

OPEN SESSION

January 17, 2002

9:30 A.M. – 5 P.M.

Hilton Washington DC North/Gaithersburg
Salons A, B, and C
620 Perry Parkway
Gaithersburg, MD

9:30 AM Call to Order Jayne S. Weiss, M.D. - Acting Chair

Introductory Remarks Sara M. Thornton - Executive Secretary

Conflict of Interest Statement

Appointment to Temporary Voting Status

9:45 - 10:15

OPEN PUBLIC HEARING

OPEN COMMITTEE SESSION

Jayne S. Weiss, M.D., Acting Chair

10:15 - 10:30

BRANCH UPDATES

Donna R. Lochner
Chief, Intraocular and Corneal Implants Branch

PMA P010059

10:30 - 11:30

SPONSOR PRESENTATION

11:30 - 11:45

Panel Questions for the Sponsor

11:45 - 12 Noon

FDA PRESENTATION

Donna Lochner – Introduction
Joel P. Glover – Team Leader
Bernard L. Lepri, O.D., M.S., M.Ed. - Clinical Reviewer

12 Noon – 12:15 PM

Panel Questions for FDA

12:15 - 12:20 Additional Comments From the Sponsor

12:20 - 1:20 **LUNCH**

1:20 **COMMITTEE DELIBERATIONS**

Primary Panel Reviewers: Joel Sugar, M.D.
Woodford S. Van Meter, M.D.

PANEL DISCUSSION OF P010059
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

5:00 PM OPEN MEETING ADJOURNED

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