

OPHTHALMIC DEVICES PANEL

OPEN SESSION

January 18, 2002

8:30 A.M. – 3:30 P.M.

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

8:30 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

8:45 - 9:15

OPEN PUBLIC HEARING

OPEN COMMITTEE SESSION

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

PMA P870024/S043

9:15 - 10:15

SPONSOR PRESENTATION

10:15 - 10:30

Panel Questions for the Sponsor

10:30 - 10:45

FDA PRESENTATION

James Saviola, O.D. – Introduction
Eleanor McGhee – Team Leader
Bernard L. Lepri, O.D., M.S., M.Ed. - Clinical Reviewer

10:45 - 11:00

Panel Questions for FDA

11:00 - 11:15 Additional Comments From the Sponsor

11:15 - 11:45

COMMITTEE DELIBERATIONS

Primary Panel Reviewers: Timothy T. McMahon, O.D.
Timothy B. Edrington, O.D.

11:45 - 12:45

LUNCH

12:45 PM

PANEL DISCUSSION OF P870024/S043
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 PM

OPEN MEETING ADJOURNED

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