

OPHTHALMIC DEVICES PANEL

OPEN SESSION

November 30, 2001

9:45A.M. – 4:30 P.M.

Holiday Inn Gaithersburg
Walker/Whetstone Rooms
2 Montgomery Village Avenue
Gaithersburg, MD

9:45 AM Call to Order Joel Sugar, M.D. - Interim Chair

Introductory Remarks Sara M. Thornton - Executive Secretary

Conflict of Interest Statement
Appointment to Temporary Voting Status

9:50 - 10:20

OPEN PUBLIC HEARING

OPEN COMMITTEE SESSION

Joel Sugar, M.D., Interim Chair

10:20 - 10:35

FDA PRESENTATION

10:35 - 10:45

DIVISION UPDATE

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

BRANCH UPDATES

Everette T. Beers, Ph.D.
Chief, Diagnostic and Surgical Devices Branch

Donna R. Lochner
Chief, Intraocular and Corneal Implants Branch

James F. Saviola, O.D.
Chief, Vitreoretinal and Extraocular Devices Branch

PMA P010018

10:45 - 11:45

SPONSOR PRESENTATION

11:45 - 12 Noon

Panel Questions for the Sponsor

12 Noon - 1:00 PM

LUNCH

1:00 - 1:15

FDA PRESENTATION

Everette T. Beers, Ph.D. – Introduction

Joel P. Glover – Team Leader

Sheryl L. Berman, M.D. - Clinical Reviewer

1:15 – 1:30

Panel Questions for FDA

1:30 - 1:35

Additional Comments From the Sponsor

1:35

COMMITTEE DELIBERATIONS

Primary Panel Reviewers: Arthur Bradley, Ph.D.
Michael R. Grimmatt, M.D.
Jayne S. Weiss, M.D.

PANEL DISCUSSION OF P010018

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

FINAL PANEL COMMENTS

4:30 PM

OPEN MEETING ADJOURNED

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