

EAR, NOSE AND THROAT DEVICES PANEL

OPEN SESSION

PANEL AGENDA – AUGUST 16, 2002

12:30.P.M. – 4:30 P.M.

12:30 p.m. Call to order A. Julianna Gulya, M.D. - Chair
Introductory Remarks Sara M. Thornton - Executive Secretary
Conflict of Interest Statement

12:40 - 1:10 **OPEN PUBLIC HEARING SESSION**

OPEN COMMITTEE DISCUSSION SESSION

A. Julianna Gulya, M.D., Chair

1:10 - 1:15 **DIVISION UPDATE**
A. Ralph Rosenthal, M.D., Director
David M. Whipple, Deputy Director
Division of Ophthalmic and Ear, Nose, and Throat Devices

1:15 - 1:45 **BRANCH UPDATE**
Eric A. Mann, M.D., Ph.D., Chief
Ear, Nose and Throat Devices Branch

1:45 - 3:45 **FDA PRESENTATION**
Eric A. Mann, M.D., Ph.D.
Teri M. Cygnarowicz, M.A., CCC-A

IMPLANTABLE MIDDLE EAR HEARING DEVICE DRAFT GUIDANCE FOR INDUSTRY AND FDA

PANEL DISCUSSION OF QUESTIONS

3:45 - 4:15 **OPEN PUBLIC HEARING SESSION**

4:15 - 4:30 **SUMMARY REMARKS AND COMMENTS**

4:30 pm **MEETING ADJOURNED**

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