

NEUROLOGICAL DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Seventeenth Meeting
Holiday Inn
Walker/Whetstone Rooms
Two Montgomery Village Avenue
Gaithersburg, Maryland
June 15, 2004

Panel Chairperson
Kyra J. Becker, M.D.

Executive Secretary
Janet L. Scudiero, M.S.

8:00 am Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update since the February 23, 2004 Meeting
Theodore R. Stevens, Chief, Restorative Devices Branch (REDB)

**Cyberonics, Inc., Implanted Vagus Nerve Stimulation System,
PMA P970003/S50**

8:15 am 1st Open Public Hearing*

9:45 am Sponsor Presentation
Alan Totah, Vice President of Regulatory Affairs, Cyberonics, Inc.
A. John, Rush, M.D., University of Texas Southwestern, Dallas, TX
Richard L. Rudolph, M.D., Vice President of Clinical and Medical
Affairs and Chief Medical Officer, Cyberonics, Inc.

11:15 am Break

11:30 am FDA Presentation
Carlos L. Peña, Ph.D.
Michael J. Schlosser, M.D.
Chang S. Lao, Ph.D., Division of Biostatistics

12:30 pm Lunch

1:30 pm Panel Deliberations
Philip S. Wang, M.D., M.P.H., Dr. P.H.
Jonas H. Ellenberg, Ph.D.

3:45 pm 2nd Open Public Hearing*

4:15 pm Break

4:30 pm FDA and Sponsor Summations, up to 15 minutes each

5:00 pm Panel Vote

6:00 pm Adjournment

* **Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.