

DRAFT

**NEUROLOGICAL DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE**

Twelfth Meeting

**9200 Corporate Boulevard
Rockville, Maryland
September 16 and 17, 1999**

Panel Chairperson
Alexa I. Canady, M.D.

Executive Secretary
Janet L. Scudiero, M.S.

September 16, 1999

- 11:00 am** **Call to Order**
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update Since the June 1998 Meeting
- 11:30 am** **Draft "Guidance Document for Dura Substitute Devices"**

Open Public Hearing, 30 minutes
FDA Presentation
Industry Presentation
- 12:15 pm** **Lunch**
- 1:15 pm** **Draft "Guidance Document for Dura Substitute Devices", continued**
FDA Questions
Panel Discussion
Panel Recommendations
- 3:00 pm** **Break**
- 3:15 pm** **Classification of Human Dura Mater Devices**

Open Public Hearing, 30 minutes
Background
FDA Presentation
Industry Presentation
FDA Questions
Panel Discussion
Open Public Hearing, near the end of the panel's deliberations, 30 minutes
Concluding Panel Discussion, Completion of the Classification
Questionnaire and Supplemental Data Sheet, and Vote
- 6:00 pm** **Adjournment**