

Neurological Devices Panel for the Medical Devices Advisory Committee

**Hilton Washington, DC/North. Salons A-D of Ballroom
March 21, 2019**

**Discuss and make recommendations on a DeNovo application for a device to treat mild to moderate
Alzheimer disease**

Panel Chairperson:
Mary E. Jensen, M.D.

Designated Federal Officer
Aden S. Asefa, M.P.H.

8:00	a.m.	Call to Order Conflict of Interest Panel Introductions
8:15	a.m.	Welcome & Introduction (FDA)
8:30	a.m.	Neuronix, Ltd. Presentations (90 min) Questions to Neuronix, Ltd. (15 min)
10:15	a.m.	Break
10:30	a.m.	FDA Presentation (90 min) Questions to FDA (15 min)
12:15	p.m.	Lunch
01:00	p.m.	*Open Public Hearing
02:00	p.m.	Panel Deliberations
03:30	p.m.	Break
03:45	p.m.	FDA Questions/Panel Deliberations Cont.
04:30	p.m.	Summary of Panel Recommendations
05:00	p.m.	Adjourn

*** Open Public Hearing** – 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.