



## **Neurological Devices Panel for the Medical Devices Advisory Committee**

**Hilton Washington, DC/North. Salons A-D of Ballroom  
March 1, 2018**

**Discuss and make recommendations regarding the evaluation of clinical study data to support the safety and effectiveness of intracranial aneurysm treatment devices and factors that can affect clinical outcomes.**

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

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

<b>8:00</b>	<b>a.m.</b>	<b>Call to Order Conflict of Interest Panel Introductions</b>
<b>8:15</b>	<b>a.m.</b>	<b>Welcome &amp; Introduction (FDA)</b>
<b>8:30</b>	<b>a.m.</b>	<b>FDA Presentation (40 min)</b> <i>Speakers: Samuel Raben, PhD; Patrick Noonan, Jr., MD</i>
		<b>Questions to FDA (20 min)</b>
<b>9:30</b>	<b>a.m.</b>	<b>Device Manufacturers</b>
<b>10:30</b>	<b>a.m.</b>	<b>Break</b>
<b>10:45</b>	<b>a.m.</b>	<b>Professional Organizations</b>
<b>11:30</b>	<b>a.m.</b>	<b>Open Public Hearing*</b>
<b>12:30</b>	<b>p.m.</b>	<b>Lunch</b>
<b>01:30</b>	<b>p.m.</b>	<b>FDA Questions/Panel Deliberations</b>
<b>03:30</b>	<b>p.m.</b>	<b>Break</b>
<b>03:45</b>	<b>p.m.</b>	<b>FDA Questions/Panel Deliberations Cont.</b>
<b>05:00</b>	<b>p.m.</b>	<b>Summary of Panel Recommendations</b>
		<b>Adjourn</b>

**\* 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.