

# AGENDA

*September 20, 2007 Atrial Fibrillation Trial Issues*

**Circulatory System Devices Panel  
Hilton Washington DC North/Gaithersburg  
Gaithersburg, MD**

**Panel Chairperson**  
Clyde Yancy

**Executive Secretary**  
James Swink

|              |           |   |
|--------------|-----------|---|
| <b>8:00</b>  | <b>am</b> | <b>Call to Order<br/>Panel Introductions</b>  |
| <b>8:15</b>  | <b>am</b> | <b>Open Public Hearing*</b>   |
| <b>8:45</b>  | <b>am</b> | <b>Q &amp; A</b>  |
| <b>9:00</b>  | <b>am</b> | <b>FDA Presentation</b>   |
| <b>10:00</b> | <b>am</b> | <b>FDA Q &amp; A</b>  |
| <b>10:15</b> | <b>am</b> | <b>BREAK</b>  |
| <b>10:30</b> | <b>am</b> | <b>Open Public Hearing*<br/>(Each manufacturer will discuss their experience with Afib)</b> |
| <b>11:30</b> | <b>am</b> | <b>Q &amp; A</b>  |
| <b>11:45</b> | <b>am</b> | <b>Lunch</b>  |
| <b>12:45</b> | <b>pm</b> | <b>FDA Questions &amp; Panel Deliberations</b>  |
| <b>3:00</b>  | <b>pm</b> | <b>BREAK</b>  |
| <b>3:15</b>  | <b>pm</b> | <b>Second Open Public Hearing*</b>  |
| <b>3:45</b>  | <b>pm</b> | <b>Q &amp; A</b>  |
| <b>4:00</b>  | <b>pm</b> | <b>Panel Recommendations</b>  |
| <b>5:30</b>  | <b>pm</b> | <b>Adjourn</b>  |

\* **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.