



FDA Circulatory System Devices Panel Advisory Committee Meeting

June 19 & 20, 2019

Gaithersburg Holiday Inn, Grand Ballroom

2 Montgomery Village Avenue
Gaithersburg, Maryland 20879

The committee will discuss and make recommendations on information related to recent observations of increased long-term mortality in peripheral arterial disease patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared to patients treated with uncoated comparator devices. FDA requests panel input regarding the presence and magnitude of the signal and potential causes. FDA also seeks input regarding appropriate regulatory actions associated with the findings.

Day 2 - June 20, 2019

8:00 a.m.	Call to Order and Opening Remarks Introduction of the Committee	Richard Lange., MD Panel Chair
8:05 a.m.	Conflict of Interest Statement	Evella Washington Designated Federal Officer

Agency Presentation

8:15 a.m.	Introduction/Background/Clinical/Animal
9:00 a.m.	Clarifying Questions from the Panel

Manufacturer Presentation

9:15 a.m.	Combined Manufacturer Presentation
9:45 a.m.	Clarifying Questions from the Panel
10:00 a.m.	Break
10:15 a.m.-11:30 a.m.	*Open Public Hearing Session 2

11:30 a.m.	Clarifying Questions from the Panel
11:45 a.m.	Lunch
12:30 p.m.	FDA Questions/Panel Deliberation (continued)

2:45 p.m. Summary of Panel Recommendation

3:00 p.m. Day 2 Adjourns

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* **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.