



**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 1 - June 19, 2019**

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

**FDA Presentation**

8:15 a.m.	FDA Presentation – DAY 1	<b>Eleni Whatley, PhD</b> Lead Reviewer  <b>Adrijo Chakraborty, PhD</b> Mathematical Statistician  <b>Yu Zhao, PhD</b> Mathematical Statistician  <b>Donna Buckley, MD</b> Interventional Radiologist
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9:15 a.m. Clarifying Questions from the Panel

9:30 a.m. Break

**Manufacturers Presentations**

9:45 a.m.	<b>Combined Industry Presentation</b>	
10:00 a.m.	Cook Medical <b>Zilver PTX Drug-Eluting Stent</b>	<b>Aaron Lottes, PhD</b> <b>Michael Dake, MD</b>
10:15 a.m.	BD/BARD/Lutonix, Inc. <b>Lutonix Drug Coated Balloon</b>	<b>JD Meler, MD</b> <b>Kenneth Ouriel, MD</b>
10:30 a.m.	Medtronic, Inc. <b>IN.PACT Admiral Drug Coated Balloon</b> Introduction Safety Analysis Benefit Risk	<b>Simona Zannetti, MD</b> <b>Laura Mauri, MD, MSc</b> <b>Peter Schneider, MD</b>
	Philips <b>Stellarex</b> Overview	<b>Jonathan Batiller</b> Head of Medical and Clinical Affairs
10:45 a.m.	Clinical Data	<b>William Gray, MD</b> Chief of CV Services President, Lankenau Heart Institute
11:00 a.m.	Boston Scientific Corporation	<b>Ian Meredith, MD</b> Executive VP and Global Chief Medical Officer  <b>Robert A. Lookstein, MD</b> Professor of Radiology and Surgery Vice Chair and Chief, Division of Interventional Radiology Mount Sinai Medical Center
11:15 a.m.	Clarifying questions from the Panel	
11:30 a.m.	<i>Lunch</i>	
12:15 -1:50p.m.	<b>*Open Public Hearing Session 1</b>	
2:00 p.m.	Break	
2:15 p.m.	FDA Questions: Questions 1-5 Panel Deliberations	<b>Eleni Whatley, PhD</b> Lead Reviewer
4:45 p.m.	Summary of Panel Recommendation	
5:15 p.m.	Day 1 Adjourns	

\* **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.