



CIRCULATORY SYSTEM DEVICES PANEL

*January 25, 2011*  
*AED 515(i) General Issues Meeting*  
Gaithersburg Holiday Inn  
Gaithersburg, MD

**Panel Chairperson**  
John Hirshfeld, M.D.

**Designated Federal Officer**  
James Swink

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|--------------|-----------|---|
| <b>8:00</b>  | <b>am</b> | <b>Call to Order</b><br><b>Conflict of Interest and Deputization to Voting Member Status Statements</b><br><b>Panel Introductions</b>   |
| <b>8:15</b>  | <b>am</b> | <b>Post Market Update</b><br><i>Danica Marinac-Dabic, MD, PhD</i><br><i>Director, Division of Epidemiology</i>  |
| <b>8:30</b>  | <b>am</b> | <b>FDA Presentation</b>   |
| <b>10:00</b> | <b>am</b> | <b>FDA Q &amp; A</b>  |
| <b>10:30</b> | <b>am</b> | <b>Break</b>  |
| <b>10:45</b> | <b>am</b> | <b>Panel Deliberations</b>  |
| <b>12:00</b> | <b>pm</b> | <b>Lunch</b>  |
| <b>1:00</b>  | <b>pm</b> | <b>Open Public Hearing*</b> <ul style="list-style-type: none"><li>➤ <i>Paula Lank, Vice President of Regulatory and Clinical Affairs at Physio-Control</i></li><li>➤ <i>Diana Zuckerman, PhD., National Research Center for Women &amp; Families and Cancer Prevention and Treatment Fund</i></li><li>➤ <i>Tamara Yount, Phillips Medical</i></li></ul> |
| <b>2:00</b>  | <b>pm</b> | <b>FDA Questions</b>  |
| <b>4:00</b>  | <b>pm</b> | <b>Break</b>  |
| <b>4:15</b>  | <b>pm</b> | <b>FDA Questions</b>  |
| <b>5:45</b>  | <b>pm</b> | <b>FDA Summation</b>  |
| <b>6:00</b>  | <b>pm</b> | <b>Adjournment</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.