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

8:00 am Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions

8:15 am Post Market Update
Danica Marinac-Dabic, MD, PhD, Director, Division of Epidemiology

8:30 am FDA Presentation
- Marjorie Shulman, Program Operations Staff, ODE
- Oscar Tovar, M.D., Lead Reviewer, ODE
- Roberta Sullivan, BSN, MPH, Medical Device Reports, OSB
- Bradley Quinn, BME, Office of Compliance, ODE
- John Sapirstein, M.D., Clinical Reviewer, ODE

10:00 am FDA Q & A

10:30 am Break

10:45 am Panel Deliberations

12:00 pm Lunch

1:00 pm Open Public Hearing*
- Paula Lank, Vice President of Regulatory and Clinical Affairs at Physio-Control
- Diana Zuckerman, PhD., National Research Center for Women & Families and Cancer Prevention and Treatment Fund
- Paul Smolenski, Senior Director Quality and Regulatory Affairs
  Carl Morgan, Scientist, Phillips Medical

2:00 pm Panel Deliberations & FDA Questions

3:30 pm Break

3:45 pm FDA Questions

6:00 pm Adjournment

* 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.