

AGENDA
MEDICAL DEVICES DISPUTE RESOLUTION PANEL

December 15, 2006

Hilton Washington DC North, Salons A, B and C, 620 Perry Parkway, Gaithersburg MD

8:00 a.m. – 5:00 p.m.	Dispute Presentations, Discussion, Recommendation and Vote Convened to hear a scientific dispute between FDA and Acorn Cardiovascular, Inc. related to the approvability of a premarket approval application (PMA) for the CorCap Cardiac Support Device for patients with dilated cardiomyopathy.
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8:00-8:15	Call to Order	Scott Ramsey, M.D., Ph.D. Panel Chair
8:15-8:45	Open Public Hearing *	
8:45-10:15	Acorn Presentation	
10:15-10:30	Break	
10:30-12:00	FDA Presentation	
12:00-12:45	Lunch	
12:45-1:00	Acorn Follow-up/Rebuttal	
1:00-1:15	FDA Follow-up/Rebuttal	
1:15-1:45	Open Public Hearing*	
1:45-3:30	Open Committee Discussion (including any panel questions of, and requests for clarification from, Acorn and FDA).	
3:30-3:40	Break	
3:40-3:50	FDA Summation	
3:50-4:00	Acorn Summation	
4:00-5:00	Panel Deliberation and Vote	
5:00	Adjourn	

* OPEN PUBLIC HEARINGS: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Panel. The Executive Secretary will present the speakers who have requested time for a presentation. After the scheduled speakers have spoken, the Chair may ask them to remain if the Panel wishes to question them further. The Chair will recognize unscheduled speakers as time allows. Note: Only the Chair and members of the Panel may question speakers during the open public hearings.