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**GENERAL AND PLASTIC SURGERY DEVICES PANEL**  
**AGENDA****GENERAL AND PLASTIC SURGERY DEVICES PANEL**  
**of the**  
**MEDICAL DEVICES ADVISORY COMMITTEE**  
Hilton Washington DC North/Gaithersburg  
620 Perry Parkway, Gaithersburg, MD**August 30, 2011****Panel Chairperson**

Joseph LoCicero III, M.D.

**Designated Federal Officer**

James Swink

8:00 AM	Call to Order Panel Introductions Conflict of Interest Statement Panel Update
8:15 AM	Introduction (Background for meeting, PR background—roll outs, etc.)
8:30 AM	DEPI Overview of PAS Program
8:45 AM	BI PAS Update and Discussions of Future Studies--FDA a. Premarket input on current S&E b. PAS Update
9:30 AM	Q & A for FDA
10:00 AM	BREAK
10:15 AM	Allergan Presentation <b>30 min</b>
10:45 AM	Mentor Presentation <b>30 min</b>
11:15 AM	Q &A to Allergan and Mentor
12:00 PM	Lunch
1:00 PM	<b>Open Public Hearing*</b>
3:00 PM	Break
3:15 PM	Future PAS Study Designs--FDA
4:00 PM	Q&A for FDA
4:20 PM	Panel Questions with discussion (FDA and panel)
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.



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*AGENDA*

GENERAL AND PLASTIC SURGERY DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE  
Hilton Washington DC North/Gaithersburg  
620 Perry Parkway, Gaithersburg, MD

August 31, 2011

**Panel Chairperson**

Joseph LoCicero III, M.D.

**Designated Federal Officer**

James Swink

8:00 AM	Call to Order Panel Introductions Conflict of Interest Statement
8:15 AM	<i>Recap of day 1 (FDA) How much time is needed Issues</i>
8:30 AM	<i>Open Public Hearing*</i>
10:30 AM	BREAK
10:45 AM	Review of Panel questions (continue where we left off)
12:00 PM	Lunch
1:00 PM	Panel Deliberations
3:00 PM	FDA Summary ( <i>Allergan/Mentor Final Comments?</i> )
3:30 PM	Summary comments solicited from panel
4:00 PM	Adjourn

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