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**From:** Tiffany, Deborah  
**To:** 'Silva, Laura'; Alison Sherwood; Allen T. Bagatsing; Apurva Saraf; Augustine Frimpong; Beth Brannan; Bob Rice; Chris Uhrn; Colin D'Cuhna; Coplan, Paul; Delehant, Todd; Elizabeth Ernst; Eric Davis; Smith, Eric; Gary Kozloski; Greg Hicks; Haddox, Dr. J. David; James Osborne ; James Ottinger; Jean-Yves Maziere; Jill A. Olexa; Buckley, Jill; Jill McCollam; Joel Novendstern; John Lay; Kiran Krishnan; Kishore Gopu; Laura Pethick; Lee Snyder; Linda Kitlinski; Linda Noa; Lofton, Melissa; Michael B. Clark; Michael Greene; Monique Weitz; Robert Barto; Sean Russel; Sherice Mills; Susan Hamet; Susan Nicholson; Tara Chapman; Terri Nataline  
**CC:** Joe Lynch; John Carroll; Peter Todaro; Landau, Dr. Craig; Scott Tomskey; Alexander, Justin; Crudele, Nancy; Law - Andrea Kochensparger; Stanton, Marsha; Pickett, Larry; Rosen, Burt; Vendor - Kishore Gopu  
**Sent:** 7/11/2011 4:10:00 PM  
**Subject:** RE: REMS & REMS SD Ready for IWG Review and IWG F2F Meeting Agenda for July 13-14 is attached  
**Attachments:** FINAL Agenda\_for\_13\_14\_July\_11\_IWG\_Mtg\_v3.docx

Dear IWG,

Also, please find attached the FINAL Agenda for the IWG F2F Meeting on July 13-14 at the Philadelphia Airport Marriott.

Ops Subteam

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**From:** Silva, Laura [mailto:Laura.Silva@pharma.com]  
**Sent:** Monday, July 11, 2011 4:13 PM  
**To:** Alison Sherwood; Allen T. Bagatsing; Apurva Saraf; Augustine Frimpong; Beth Brannan; Bob Rice; Chris Uhrn; Colin D'Cuhna; Coplan, Paul; Delehant, Todd; Elizabeth Ernst; Eric Davis; Smith, Eric; Gary Kozloski; Greg Hicks; Haddox, Dr. J. David; James Osborne ; James Ottinger; Jean-Yves Maziere; Jill A. Olexa; Buckley, Jill; Jill McCollam; Joel Novendstern; John Lay; Kiran Krishnan; Kishore Gopu; Laura Pethick; Lee Snyder; Linda Kitlinski; Linda Noa; Lofton, Melissa; Michael B. Clark; Michael Greene; Monique Weitz; Robert Barto; Sean Russel; Sherice Mills; Susan Hamet; Susan Nicholson; Tara Chapman; Terri Nataline  
**Cc:** Joe Lynch; John Carroll; Peter Todaro; Tiffany, Deborah; Landau, Dr. Craig; Scott Tomskey; Silva, Laura; Alexander, Justin; Crudele, Nancy; Law - Andrea Kochensparger; Stanton, Marsha; Pickett, Larry; Rosen, Burt; Vendor - Kishore Gopu  
**Subject:** REMS & REMS SD Ready for IWG Review

Dear IWG colleagues,

The REMS and REMS Supporting Document have been updated and are available for your review. The revised documents are located on the IWG SharePoint site in the REMS and REMS Supporting Document folder, Third Draft subfolder, titled:

- IWG Proposed Opioid REMS 11Jul11\_All Comments.docx
- IWG Proposed Opioid REMS SD 11Jul11\_All Comments.docx

As a reminder, we will be reviewing the documents in detail at the face-to-face meeting on July 13<sup>th</sup> & 14<sup>th</sup>. This will be the final opportunity for substantial comments. For any areas where a consensus is not reached, a vote will be taken at the meeting (votes taken at the meeting will be binding)

We look forward to seeing everyone in Philadelphia on Wednesday

Kind regards,

Operations Subteam

PLAINTIFFS TRIAL  
EXHIBIT  
**P-28854\_00001**

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P-28854 \_ 00001

**Industry Working Group (IWG) Face-to-Face Meeting**  
**July 13-14, 2011**  
**Meeting Location: Philadelphia Airport Marriott**  
**Wednesday, July 13, Meeting Room - Salon G**  
**Thursday, July 14, Meeting Room 5; Legal Break-Out, Meeting Room 3**  
**Dial In: 800-326-0013**  
**Conf ID: 1058120**

<b>TIME</b>	<b>AGENDA TOPIC</b>	<b>SPEAKER/ FACILITATOR</b>
	<b>DAY 1, WEDNESDAY, JULY 13<sup>th</sup> , SALON G</b>	
<b>7:30 – 8:00 AM</b>	<b>Registration and Continental Breakfast</b>	<b>Communal breakfast 7-9 AM</b>
<b>8:00 – 8:15 AM</b>	<b>Welcome &amp; Review of Antitrust Guidelines</b>	<b>King &amp; Spaulding</b>
<b>8:15 – 8:30 AM</b>	<b>Goal / Outcome of the Meeting</b> <ul style="list-style-type: none"> <li>• Finalize REMS/REMS Supporting Document</li> <li>• Project Management Vendor presentations</li> <li>• Program Agreement discussion</li> </ul>	<b>S. Nicholson</b>
<b>8:30 – 10:00 AM</b>	<b>Review of REMS Supporting Document</b> <ul style="list-style-type: none"> <li>• Title Page/Confirmation of IWG Participants</li> <li>• Definitions</li> <li>• Background</li> <li>• Goals</li> <li>• REMS Elements <ul style="list-style-type: none"> <li>○ Medication Guide</li> <li>○ Elements to Assure Safe Use <ul style="list-style-type: none"> <li>▪ Prescriber Training</li> <li>▪ Patient Education Materials</li> <li>▪ Prescriber Notification of REMS</li> </ul> </li> </ul> </li> </ul>	<b>S. Nicholson / Sub-team Leads</b>
<b>10:00 – 10:15 AM</b>	<b>Morning Break</b>	
<b>10:15 – 12:00 PM</b>	<b>Review of REMS Supporting Document (cont'd)</b> <ul style="list-style-type: none"> <li>○ Timetable</li> <li>○ Information Needed for Assessments <ul style="list-style-type: none"> <li>▪ REMS Assessment Plan</li> <li>▪ Reporting</li> </ul> </li> <li>○ Appendices <ul style="list-style-type: none"> <li>▪ Appendix 2 – Blueprint</li> <li>▪ Appendix 3.1 – Outline of Patient Education</li> <li>▪ Appendix 3.2 – PMIS</li> <li>▪ Appendix 4.1 – Dear DEA-Registered Prescriber</li> <li>▪ Appendix 4.2 – Dear Licensing Boards and Assoc. Letter</li> </ul> </li> </ul>	<b>S. Nicholson / Sub-team Leads</b>
<b>12:00 – 1:00 PM</b>	<b>Lunch</b>	

**Industry Working Group (IWG) Face-to-Face Meeting**  
**July 13-14, 2011**  
**Meeting Location: Philadelphia Airport Marriott**  
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**Thursday, July 14, Meeting Room 5; Legal Break-Out, Meeting Room 3**  
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**Conf ID: 1058120**

<b>TIME</b>	<b>AGENDA TOPIC</b>	<b>SPEAKER/ FACILITATOR</b>
<b>1:00 – 2:00 PM</b>	<b>Project Management (PM) Vendor 1 Presentation</b>	<b>Vendor Sub-team</b>
<b>2:00 – 2:15 PM</b>	<b>Break</b>	
<b>2:15 – 3:15 PM</b>	<b>PM Vendor 2 Presentation</b>	<b>Vendor Sub-team</b>
<b>3:15 – 3:30 PM</b>	<b>Afternoon Break</b>	
<b>3:30 – 4:30 PM</b>	<b>PM Vendor 3 Presentation</b>	<b>Vendor Sub-team</b>
<b>4:30 – 5:30 PM</b>	<b>PM Vendor 1, 2, 3 Presentation De-Briefs</b>	<b>Vendor Sub-team</b>
<b>5:30 – 6:00 PM</b>	<b>Sub-team meetings as needed</b>	
	<b>DAY 2, THURSDAY, JULY 14<sup>th</sup>, MEETING ROOM 5</b>	
<b>7:30 – 8:00 AM</b>	<b>Registration and Continental Breakfast</b>	<b>Communal breakfast 7-9</b>
<b>8:00 – 8:15 AM</b>	<b>Welcome &amp; Review of Antitrust Guidelines</b>	<b>King &amp; Spaulding</b>
<b>8:15 – 8:30 AM</b>	<b>Review of Day 1 Action Items</b>	<b>Operations Sub-team</b>
<b>8:30 – 9:15 AM</b>	<b>Final Discussion on REMS Supporting Document (if needed)</b>	<b>IWG</b>
<b>9:15 – 10:00 AM</b>	<b>Review of REMS</b>	<b>S. Nicholson / Sub-team Leads</b>
<b>10:00 – 10:15 AM</b>	<b>Morning Break</b>	
<b>10:15 – 12:15 PM</b>	<b>Program Agreement discussion</b>	<b>Legal Sub-team</b>
<b>12:15 – 1:00 PM</b>	<b>Lunch</b>	
<b>1:00 – 2:00 PM</b>	<b>Prep for FDA Teleconference at 3:30 PM</b>	<b>Regulatory Sub-team</b>
<b>2:00 – 2:15 PM</b>	<b>Afternoon Break</b>	
<b>2:15 – 2:45 PM</b>	<b>Review of Day 2 Action Items</b>	<b>Operations Sub-team</b>
<b>2:45 – 3:30 PM</b>	<b>Final Prep for FDA Teleconference</b>	<b>Regulatory Sub-team</b>
<b>3:30 – 5:00 PM</b>	<b>FDA Teleconference</b>	