

1 **Minutes of the DPTC Teleconference**  
2 **on 17 October 2005**

3 **ATTENDEES**

Terry Tougas, <i>Chair</i> (Boehringer-Ingelheim, IPAC-RS)	Lee Nagao (IPAC-RS Secretariat)
Tony Amann (ACN Pharma, GPhA)	Russel Somma (IPS, ISPE)
Sylvia Gantt (PQRI Executive Secretary)	Bob Seevers (Eli Lilly, PhRMA?)
Michael Golden (GSK, IPAC-RS)	Bob Wiens (Eli Lilly, IPEC)
Lana Lyapustina (IPAC-RS Secretariat)	Bruce Wyka (Schering-Plough, IPAC-RS)

4 **AGREEMENTS**

- 5 1. The proposed agenda for the 4 November meeting is approved.
- 6 2. Draft report on RFID will be provided to DPTC for review in the next week.

7 **DISCUSSION SUMMARY**

8 *Opening*

9 Dr. Tougas opened the teleconference and read the following antitrust admonition: “Our  
10 discussions today are subject to the anti-trust guidance applicable in the U.S. and E.U.  
11 Nothing discussed at this meeting is intended to restrict the individual decision-making of  
12 any member company or to represent an agreement to coordinate marketing or sales conduct.  
13 Those participating in this meeting are instructed to avoid discussion of competitively  
14 sensitive subjects, including, but not limited to, confidential marketing, sales, and pricing  
15 information.”

16 The objective of the teleconference was to update on all of the DPTC Working Groups.

17 *The RFID Working Group*

18 A status report about the RFID effort has been drafted for Ms. Winkle, as she had requested  
19 in a meeting about 4-6 weeks ago, in which the following participated: Ms. Winkle, Drs.  
20 Massa, Seevers, Poochikian and Clark. The draft report will be provided to the DPTC for  
21 review in the next week and will be discussed for approval during the 4 November meeting.

22 *The Mass Balance Working Group*

23 The Working Group has drafted slides for presentation at the DPTC 4 November meeting.  
24 An executive summary and supporting documents from that group have been forwarded to  
25 Ms. Winkle per her request, as discussed at a previous Steering Committee meeting.

26 ***The Leachables and Extractables Working Group***

27 The complete L&E Recommendations are being reviewed by the FDA members of the  
28 Working Group. The hope is to provide the document to the DPTC at end of October-early  
29 November.

30 The L&E Workshop on 5-6 December had 43 registrants as of last week. Working Group  
31 members and FDA representatives will be among the speakers. Everyone is encouraged to  
32 attend.

33 ***The Container Closure Working Group***

34 No updates were available at this teleconference.

35 ***The PSD Profiles Comparisons Working Group***

36 The Working Group is aiming to complete the substance of the Recommendations by the end  
37 of this year. This week, the WG members will together make equivalent/inequivalent  
38 assignments for the realistic profiles, and then the outcomes of the proposed statistical tests  
39 could be compared with these designations. Finalization and submission of the  
40 Recommendations to FDA is planned for early 2006.

41 ***The Excipients Working Group***

42 As of last Friday, 10/14, when the survey ended, there had been 122 responses (17 from  
43 excipient manufacturers, 4 from distributors and 101 from users). For confidentiality  
44 reasons, the identity or size of companies which participated in the survey cannot be known,  
45 but the distinction between US-only and global businesses will be known.

46 The final statistics will be provided later. The analysis will be able to draw out different  
47 perspectives on the same question by different parties (e.g., an assessment of audits by the  
48 users and manufacturers). The results are expected to clarify current regulatory  
49 understanding and any gaps that need to be addressed.

50 The DPTC congratulated the Working Group on this important milestone.

51 **NEXT MEETING/TELECONFERENCE**

52 Face to face meeting on 4 November at Rockwall II – Room 1033, 5515 Security Lane,  
53 Rockville, MD

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Finalized on 9 November 2005