

Minutes of the DPTC Teleconference on 5 March 2007

Opening

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

Leachables and Extractables

- PDA is interested in extending the L&E approach to parenterals. A specific proposal will be provided to the DPTC for a 2-week review in the near future.

Container Closure Working Group

- The 90-day data collection has been completed and forwarded to the WG statistician for analysis.
- Protocol for blister packaging (based on the moisture vapor transfer concept) will be finalized shortly and provided to the DPTC for comment. The blister packaging experiment will be started in the next 3-4 weeks. All materials are available and the study only needs to be fitted into the manufacturing schedule.

Profile Comparisons

- The Working Group’s “interim report” papers have been published in *AAPS PharmSciTech* in the first issue of 2007.
(<http://www.aapspharmscitech.org/default/issueView.asp?vol=08&issue=01>)
- The WG’s manuscript for the “final report” has been reviewed and approved by the DPTC. The WG is now preparing the paper for the SC review (within the next couple of weeks) and subsequent submission to the *AAPS PharmSciTech*. Upon acceptance of the paper for publication, the Working Group will prepare a letter to the SC and FDA, indicating completion of its work.

Excipients

- A complete report of the October 2006 Workshop is being prepared for publication in *Pharmaceutical Technology*. The DPTC approval of the manuscript will be sought in April 2007, with planned submission to the journal in April-May.
- FDA has invited the WG to discuss skip testing and other recommendations at a face-to-face meeting on March 26. A position paper will be prepared based on these discussions.

36 The DPTC requested that the WG provide to the DPTC its materials for the meeting and
37 the minutes.

- 38 • A final report will be forwarded to the SC in May-June. With the submission of the
39 report to CDER, the mission of the Working Group will be completed.

40 ***Mass Balance***

- 41 • The Working Group is awaiting a response from FDA regarding its 2006 submission.
- 42 • The WG's paper has been accepted for publication in the *Journal of Aerosol Medicine*
43 and should appear in 2007.

44 ***Specifications Design and Life Cycle Management***

- 45 • The DPTC nominees to the Working Group were selected based on their field of
46 expertise and the WG needs.
- 47 • The WG held a kick-off face-to-face meeting and has already scheduled the next meeting
48 and teleconference.
- 49 • The WG leadership will be asked to participate in DPTC teleconferences going forward.

50 ***Stability & Shelf Life***

- 51 • The WG prepared a detailed workplan during its face-to-face meeting. The workplan
52 will be forwarded to the DPTC for a 2-week review and approval shortly.
- 53 • FDA is aware of the WG work and has been encouraged to nominate direct
54 representatives to the WG.

55 ***Other Business***

- 56 • The PQRI SC is considering a restructuring of the Technical Committees.
- 57 • The DPTC Chair has been invited to present at a PDA conference. Slides for this
58 presentation have been provided to the DPTC members.

59 Finalized on 27 March 2007