

Drug Product Technical Committee

December 17, 2003
FDA Rockwall Building
Rockville, Maryland

MINUTES

Attendees List * denotes Chair

AAPS/Industry Representatives

*Sidney Goldstein-GPhA
Clydewyn Anthony-USP
Michael Golden-IPAC-RS (by telephone)
Robert Dana-PDA (by telephone)
Sylvia Gantt-PQRI
Chris Moreton-IPEC (by telephone)
Rich Poska-PhRMA (by telephone)
Russell Somma-ISPE (by telephone)

FDA Representatives

Jon Clark-CDER/OPS
Guiragos Poochikian-CDER/ONDC
Rajendra Uppoor-CDER/OPS

Guests

David Christopher-PSD-PCWG (by telephone)
Lana Lyapustina-IPAC-RS (by telephone)
Lee Nagao-IPAC-RS (by telephone)
Daniel Norwood-L&EWG (by telephone)

Absentees

Thomas Garcia-BUWG
Devinder Gill-CDER/OGD
Daniel Malinowski-C/CSWG
Terry Tougas-PSD-MBWG

Approval of Minutes

The minutes of October 22, 2003 were approved and are on the PQRI website.

Blend Uniformity Working Group Status

The data mining publication was submitted to the PDA journal by Joep Timmermans on December 3rd, 2003. The attendance at the Blend Uniformity Workshop held December 4&5 was 168. The presentations plus a summary of the feedback from the breakout

sessions are on the PQRI website. The BUWG members will be available to assist the FDA in finalizing the guidance document, should their service be requested.

BUWG-New Technology Sub-Group

No change in status.

Container/Closure Systems Working Group Status

No change in status.

PSD Mass Balance Working Group Status

The data mining effort has come to a standstill pending resolution of questions regarding data protection and confidentiality. There is also a concern whether the final recommendation will increase industry burden.

PDA Profile Comparisons Working Group Status

The presentation targeted for the Respiratory Drug Delivery Conference is in review by this working group. This publication will outline the complications observed with the methodology in the current guidance and alternative methodology to address these complications.

Leachables/Extractables Working Group Status

The Barnett conference was a success particularly in familiarizing the attendees regarding PQRI. The following two poster abstracts which will be presented at the Respiratory Drug Delivery Conference have been approved by the DPTC and forwarded to the PQRI-SC for their review: 1) Developing Safety Qualification Thresholds for Leachables in OINDP and 2) Experience with Extractables Profiling of Elastomers and Polymers.

A draft toxicology threshold document is in review by a panel of experts prior to submitting it to the DPTC.

The analytical results from seven laboratories should be completed by the first quarter of 2004.

Excipient Control Working Group

Sylvia Gantt will issue a memo to the PQRI SC members requesting recommendations to populate this new working group.