

Drug Product Technical Committee

MINUTES

Wednesday May 12, 2004
FDA Rockwall Building

Attendees List - **denotes Chair*

AAPS/Industry Representatives

*Sidney Goldstein-GPhA
Clydewyn Anthony-USP
Michael Golden-IPAC-RS
Robert Dana-PDA
Sylvia Gantt-PQRI

FDA Representatives

Jon Clark-CDER/OPS
Guiragos Poochikian-CDER/ONDC
Frank Holcombe-CDER/OGD

Guests

Lee Nagao-IPAC-RS
Bob Wiens-EWG

Absentees

David Christopher-PSD-PC
Thomas Garcia-BU/WG
Lana Lyapustina-IPAC-RS
Daniel Malinowski-C/CSWG
Chris Moreton-IPEC
Daniel Norwood-L&EWC
Rich Poska-PhRMA
Russell Somma-ISPE
Terry Tougas-PSD-MBWG
Rajendra Uppoor - CDER/OPS
Robert Williams - AAPS

Approval of Minutes

The March 30, 2004 teleconference minutes were approved on May 5, 2004.

Container/Closure Systems Working Group Status

The DPTC had reviewed and made comments on the MVTR/Unit White paper. These comments have been compiled and will be addressed during a teleconference scheduled

for the week of May 16, 2004. The revised document will then be submitted to the PQRI SC.

PSD Mass Balance WG Status

The group is in the process of soliciting issues from companies within IPAC regarding the safe harbor for submitted data.

PSD Profile Comparisons WG Status

The evaluation of Chi Square tests to determine equivalency of profiles is on schedule. The group will evaluate the performance of these tests as a quality assurance control. Dave Christopher will summarize the Working Group activities at the PQRI SC meeting May 13, 2004.

Leachables/Extractables WG Status

The Working Group is in the process of finalizing a draft report combining the scientific qualification and safety concern thresholds proposed by the Toxicologist Subgroup with the analytical reporting threshold developed by the Chemist Subgroup. This draft is targeted to be submitted to the DPTC this fall.

Excipients Working Group Status

Raj Uppoor from CDER/OPS has been appointed to this working group. The current members will attempt to develop a research proposal that will meet the needs of both the FDA and industry.