

Drug Product Technical Committee
February 11, 2004
FDA Rockwall Building
Rockville, Maryland

MINUTES

Attendees List * denotes Chair

AAPS/Industry Representatives

*Sidney Goldstein-GPhA
Michael Golden-IPAC-RS (by telephone)
Robert Dana-PDA (by telephone)
Sylvia Gantt-PQRI
Chris Moreton-IPEC (by telephone)

FDA Representatives

Guiragos Poochikian-CDER/ONDC
Rajendra Uppoor-CDER/OPS
Frank Holcombe-CDER/OGD

Guests

David Christopher-PSD-PCWG (by telephone)
Lana Lyapustina-IPAC-RS (by telephone)
Lee Nagao-IPAC-RS (by telephone)

Absentees

Clydewyn Anthony-USP
Jon Clark-CDER/OPS
Thomas Garcia-BU/WG
Daniel Malinowski-C/CSWG
Daniel Norwood-L&EWG
Rich Poska-PhRMA
Russell Somma-ISPE (by telephone)
Terry Tougas-PSD-MBWG
Robert Williams-AAPS

Approval of Minutes

The minutes of December 17, 2003 were approved January 22, 2004.

DPTC New Member

Robert O. Williams III was approved as the AAPS representative to the DPTC.

Blend Uniformity Working Group Status

No change in status.

BUWG-New Technology Sub-Group

A FDA PAT draft guidance review team is being formed under the MTC. The NTG chair has been asked to chair this team.

Container/Closure Systems Working Group Status

A white paper prepared by a subgroup will be submitted to the working group for review and then forwarded to the DPTC/PQRI SC for approval. This paper is based on the theory that MVTR/unit dose can be used across different types of packages to evaluate comparability as a moisture barrier. This will not deal with extractables or leachables. A second subgroup is in the process of designing a screening experiment to deal with the issue of variability and to develop a protocol on how the packaging of test samples for this study should be conducted.

PSD Mass Balance Working Group Status

No data has been received to date from the data mining exercise.

The PQRI SC has appointed a team to develop a process for data collection addressing: data mining, research on marketed products, and the issue of safe harbor.

PDA Profile Comparisons Working Group Status

The RDD abstract has been accepted.

Through the previous systematic investigation of the chi-square method, it was found that the test decisions are mainly determined by stages with largest deposition; and the working group started to discuss conceptually the potential ways to alleviate this drawback and ensure equal discriminating ability across stages. One of the ideas proposed involved separating the entire profile into two categories, "inside" and "outside" the impactor.

B. Morgan has been approved by the DPTC as an additional statistician to the working group.

Leachables/Extractables Working Group Status

The RDD poster presentation and abstracts have been accepted.

The chemistry subgroup has completed a short term leachable study to determine the analytical threshold. This data will be used to support the toxicology subgroup in determining the safety level. The objective will be to harmonize the analytical threshold with the safety concern threshold.

A presentation combining chemistry and analytical data to the DPTC/PQRI SC is targeted for mid 2004.

Excipient Working Group

Three candidates for chairperson of this committee were reviewed by the DPTC and a recommendation will be submitted to the PQRI SC.

Miscellaneous Items

Members of the DPTC raised certain concerns for the current way of expansion of Working Groups. It was agreed that for the addition of a member to a working group the

Chair of the WG should present a written justification to the DPTC for their consideration and approval.