

MINUTES
Drug Product Technical Committee
May 29 2002

FDA-Woodmont 2
Rockville, Maryland

Attendees List--- denotes Chair*

AAPS/Industry Representatives:

*Sidney Goldstein-GPhA
Jeffrey Blumenstein-IPAC-RS (by telephone)
Robert Dana-PDA
Shawn Dressman-USP
Chris Moreton-IPEC (by telephone)
Richard Poska-PhRMA (by telephone)

FDA Representatives:

Guirag Poochikian-CDER/ONDC
Rajendra Uppoor-CDER/OPS

Guests

J. David Christopher-PSD-PC WG
Tom Garcia-BUWG (by telephone)
R. Hollander CCWG (by telephone)
D. Klein CCWG
S. Lyapustina-IPAC-RS (by telephone)

Absentees:

Devinder S. Gill-CDER/OGD
Sylvia Gantt-PQRI

Approval of Minutes

The minutes of April 25, 2002 were approved and will be posted on the PQRI web site.

Blend Uniformity Working Group Status

The Blend Uniformity proposal plus the data-mining report has been formatted for publication and submitted to AAPS for per review and publication.

Container/Closure Systems Working Group Status

A draft work plan was presented to the DPTC.

Kathi R. Rinesmith and Jatin J. Shah were appointed as GPhA representatives to this work group.

Action Item:

The DPTC will review this work plan for discussion at the June 25 meeting.

PSD-Profile Comparisons Working Group Status

A draft work plan was presented to the DPTC.

Action Item:

The DPTC will review this work plan for discussion at the June 25 meeting.

PSD Mass Balance Working Group Status

The initial draft of the investigational tree needs further development.

Helen Strickland was appointed as the PhRMA statistician to this work group.

Leachables/Extractables Working Group Status

The sub-team of toxicologists are researching a wide range of toxicological databases and scientific literature in order to investigate reasonable threshold values for relevant compounds and conditions.

The sub-team of chemists will develop a strategy for soliciting component materials and formulation information from suppliers in order to investigate optimal chemical methods and techniques for extractables and leachables studies.

The next DPTC meeting is scheduled for June 25, 2002 at 10:00a.m. at the FDA-Woodmont 2 Building in room F 5th floor.