

**MINUTES**  
**Drug Product Technical Committee**  
**April 25, 2002**

**FDA-Woodmont 2**  
**Rockville, Maryland**

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*Attendees List--\* denotes Chair*

AAPS/Industry Representatives:

\*Sidney Goldstein - GPhA  
Sylvia Gantt - PQRI  
Chris Moreton - IPEC (by telephone)  
Richard Poska - ISPE (by telephone)

FDA Representatives:

Devinder S. Gill - CDER/OGD (by telephone)  
Guirag Poochikian - CDER/ONDC  
Rajendra Uppoor - CDER/OPS

Guests:

J. David Christopher - PSD-PC WG (by telephone)  
Tom Garcia - BUWG (by telephone)  
Svetlana Lyapustina - IPAC-RS (by telephone)  
Lee Nagao - IPAC-RS (by telephone)  
Terrence Tougas - PSD-MB WG (by telephone)

Absentees:

Jeffrey Blumenstein - IPAC-RS  
Robert Dana - PDA  
Shawn Dressman - USP

**Approval of Minutes**

The minutes of February 28, 2002 were approved and will be posted on the PQRI web site.

**Blend Uniformity Working Group Status**

The "Use of Stratified Sampling of Blend and Dosage Units to Demonstrate Adequacy of Mix for Powder Blends" was submitted to Janet Woodcock, M.D. March 28, 2002. This document has been posted on the PQRI web site. The recommendations plus the data-mining report has been formatted for publication and approved by the DPTC.

**Action Items:** These publications will now be submitted for publication after approval from the PQRI-SC.

**Blend Uniformity Sub-Working Group Status**

The NIRVWOG/PQRI NTG revision of USP chapter <1119> on NIR Spectroscopy has been submitted to the USP.

**Container/Closure Systems Working Group Status**

This group will be meeting by telephone conference the week of May 13 to finalize a definitive work plan based on a simple internal data mining exercise that was conducted last month. GPhA

has submitted the names of two applicants which been forwarded by this working group to the DPTC for approval.

**Action Items:** Richard Hollander will submit a definitive work plan to the DPTC by May 29.

#### **PSD-Profile Comparisons Working Group Status**

David Christopher reported that this group is working on defining the tools needed to examine data. GPhA has submitted the names of two applicants which are under consideration.

**Action Items:** David Christopher will present a draft research proposal at the next DPTC meeting on May 29. He will also give a presentation on the design of the Excel Spreadsheet and the associated SAS Program.

#### **PSD Mass Balance Working Group Status**

Terry Tougas has submitted a research plan that was approved by both the DPTC and the PQRI-SC.

**Action Items:** Submit the initial draft of the investigational tree by May 13.

#### **Leachables/Extractables Working Group Status**

Dan Norwood has submitted a research plan that was approved by both the DPTC and the PQRI-SC. The Working Group will form two sub-teams, the Chemistry Team and the Toxicology Team, which will address development of identification/reporting thresholds and qualification thresholds respectively.

**Action Items:** Develop processes for testing the Working Group's hypothesis.

The next DPTC meeting is scheduled for Wednesday May 29, 2002 at 10:00 a.m. at the FDA-Woodmont 2 building in Rockville, Maryland