

**MINUTES**  
**Drug Product Technical Committee**  
**Tuesday - June 25, 2002**

**FDA**  
Woodmont 2 Building  
**Rockville, MD**

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*\* denotes Chair*

**Attendees List**

AAPS/Industry Representatives:

Sidney Goldstein, Chairman –GPhA  
Jeffrey Blumenstein - IPAC-RS (by telephone)  
Sylvia Gantt -PQRI  
Chris Moreton- IPEC (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  
S. Lyapustine - IPAC-RS (by telephone)  
L. Nagao - IPAC-RS (by telephone)  
T. Tougas - PSD-MB WG (by telephone)

Absentees:

R. Dana - PDA  
S. Dressman - USP  
T. Garcia - BU WG  
R. Hollander - CC WG  
D. Norwood - L&E WG  
R. Poska - PhRMA

**Approval of Minutes**

The minutes of May 29, 2002 were approved and will be posted on the PQRI web site.

**Blend Uniformity Working Group Status**

Stratified sampling recommendation and data mining survey publications have been submitted, reviewed and approved for publication in Pharmaceutical Science and Technology (AAPS journal).

We are awaiting the FDA's response to our recommendation.

### **Container/Closure Systems Working Group Status**

The draft work plan will be finalized by the working group in August and submitted to the DPTC for sign off.

### **PSD Profile Comparison Working Group Status**

Comments on the work plan have been submitted by the DPTC to the working group. These will be incorporated into the work plan document and resubmitted to the DPTC for sign off.

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

Based on a survey from the industry, the working group will finalize the CI MB Investigation Tree. The group will also design an experiment to identify and quantify sources of CI MB uncertainty.

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

A sub-group of chemists will develop draft experimental protocols for review by the full working group. This group will also develop a list of leachables and typical leachable levels.

The group plans to obtain finished test articles and finalize experimental protocols and identify laboratory resources by September 2002.

The next DPTC meeting is scheduled for Wednesday, August 14, 2002 at 10:00a.m. at the FDA - Woodmont 2 Building in room F—5<sup>th</sup> floor.