

**MINUTES**  
**Drug Product Technical Committee**  
**Wednesday October 23, 2002**  
**FDA Woodmont-2 Building, Rockville, MD**

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Attendees List (*\* Denotes Chair*)

AAPS/Industry Representatives:

Sidney Goldstein, Chairman - GPhA  
Jeffrey Blumenstein - IPAC-RS (by telephone)  
Robert Dana - PDA (by telephone)  
Shawn Dressman - USP  
Sylvia Gantt - PQRI  
Richard Poska - PhRMA (by telephone)  
Russell Somma - ISPE (by telephone)

FDA Representatives:

Devinder Gill - CDER/OGD (by telephone)  
Guiragos Poochikian - CDER/ONDC (by telephone)

Guests:

Will Brown-USP  
David Christopher - PSD-PCWG (by telephone)  
Thomas Garcia - BUWG (by telephone)  
Lana Lyapustina - IPAC-RS (by telephone)  
Jolyon Mitchell - PSD-MBWG (by telephone)  
Lee Nagao-IPAC-RS (by telephone)  
Daniel Norwood - L&EWG (by telephone)  
Terry Tougas - PSD-MBWG (by telephone)

Absentees:

Chris Moreton - IPEC  
Rajendra Uppoor - CDER/OPS

**Approval of Minutes**

The minutes of August 14, 2002 were approved and will be posted on the PQRI web site.

### **Blend Uniformity Working Group Status**

CDER's questions were clarified by the BUWG at the October 17, 2002 meeting, which was instrumental in FDA's decision to accept the proposal. Dr. Ajaz Hussain reviewed the events today with the Advisory Committee of Pharmaceutical Science on October 21, 2002. The next step is for the FDA to prepare a draft guidance and seek public comments.

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

The working plan was approved by the PQRI Steering Committee on October 18, 2002.

### **PDS Mass Balance Working Group Status**

The draft publication entitled "Considerations for the Development and Practice of Cascade Impaction Testing Including a Mass Balance Failure Investigation Tree" was submitted to the DPTC for review and comments. The DPTC will submit their comments to the working group by October 30, 2002. These comments should be addressed and the revised draft should be resubmitted to the DPTC so that they can circulate it to their member organizations for comments.

A survey questionnaire was also submitted to the DPTC for comments. This document will be handled as described above.

The DPTC was also updated on the status of the other ongoing activities of the PSD MB working group.

### **PDS Profile Comparison Working Group Status**

The work plan was approved by the PQRI Steering Committee on August 29, 2002. Statistical calculations and simulations are ongoing. The strategy is to: understand the behavior of Chi-square ratio using simulated data; develop effective modeling techniques to generate realistic simulated data; and develop an approach for determining data driven critical values or "goalposts".

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

The Chemistry subgroup has obtained elastomeric and plastic test articles with formulation information. They have identified several laboratories that are willing to perform experiments with representatives from the working group. The subgroup has also drafted experimental protocols for controlled

extractables studies on elastomeric and plastic test articles. The experimental work is scheduled to start in November.

The Toxicology subgroup has collected data/information from toxicological databases, current literature, and regulatory guidelines (CFR, ICH). They are developing a first draft of justification based on 5 ug qualification threshold and will include justification of reporting threshold from a toxicological perspective.

### **Miscellaneous Items**

Updating/improving USP dissolution test—PDA raised the question as to whether a review of the current USP dissolution test would be an appropriate topic for PQRI consideration. The concerns center on whether the test could be better correlated with in vivo bioavailability. Will Brown of USP noted that there is a USP Committee charged with the responsibility of considering proposed changes to the dissolution test. DPTC determined that, inasmuch as there was not a problem with an existing regulatory guidance, this topic was not appropriate for PQRI consideration as a work project.

The next DPTC meeting is scheduled for Wednesday December 18, 2002 - 10:00 a.m.-3:00 p.m. in the FDA Woodmont 2 building, 5<sup>th</sup> floor-room F.