

## Minutes

### Drug Product Technical Committee

February 28, 2002  
FDA – Woodmont 2  
Rockville, Maryland

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*Attendees - \* denotes Chair*

#### **AAPS/Industry Representatives:**

- \* Sidney Goldstein – GPhA
- Jeffrey Blumenstein – IPAC-RS (by telephone)
- Robert Dana – PDA
- Shawn Dressman – USP
- Sylvia Gantt – PQRI
- Richard Poska – ISPE (by telephone)

#### **FDA Representatives:**

- Devinder S. Gill – CDER/OGD
- Guirag Poochikian – CDER/ONDC

#### **Guests:**

- J. David Christopher – PSD-PC WG
- Tom Garcia – BUWG (by telephone)
- Svetlana Lyapustina – IPAC-RS (by telephone)
- Jerry Planchard – BUWG (by telephone)
- Lee Nagao – IPAC-RS (by telephone)
- Daniel L. Norwood – L & E WG
- Joep Timmermans – BUWG (by telephone)
- Terrence Tougas – PSD-MB WG

#### **Approval of Minutes**

The minutes of December 12, 2001 meeting were approved and will be posted on the PQRI web site.

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

Additional data has been requested, which will be submitted to David Whiteman to produce the requested categorization. Following receipt of this information, the BUWG will provide a report summarizing the data and providing their conclusions and recommendations that can be supported with the availability data. In addition, the BUWG will determine whether additional data is needed in order to expand the recommendation.

This report will then be submitted by the DPTC to the member organizations for their comments prior to submitting the report to the PQRI SC.

### **Blend Uniformity Sub-Working Group Status**

The generation and revision of the USP chapter on NIR will be circulated to the DPTC for review. All new activities by this working group will be placed on hold pending the outcome of meetings scheduled by the FDA Advisory subcommittee on Process Analytical Technology.

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

A GPhA replacement is needed for Ralph Manning. This working group is in the process of developing a proposed work plan based on supporting the PACPAC guidance.

### **Manufacturing Changes Working Group Status**

The activities of this working group are on hold pending further notice.

### **IPAC-RS Leachables and Extractables Working Group Status**

Daniel Norwood submitted a work plan to the DPTC for their review and presented an overview of the work plan at our meeting.

The plan consists of two tasks: 1) Develop a process that can be used to develop reporting and qualification thresholds. 2) Implement a process to develop thresholds.

The target date to evaluate results and build a final consensus among the working group members is May-September 2003.

### **IPAC-RS PSD Mass Balance Working Group Status**

Terrence Tougas submitted a work plan to the DPTC for their review and also presented an overview of the work plan to our meeting. The working group proposes to investigate the following hypothesis: 1a) for OINDP, the particle size distribution mass balance, as a measure of the drug substance delivered per actuation, has a larger random uncertainty per determination than the dose content uniformity test; 1b) for OINDP, particle size distribution mass balance deviates from the mean mass of drug substance delivered from the value due to systematic uncertainties from multiple sources; and 2) orally inhaled and nasal drug products do not consistently meet the mass balance acceptance criterion of between 85 and 115 percent of label claim on a per actuation/spray basis. Appropriate mass balance limits should be based on data and method capability.

Work is expected to be completed by mid 2003 and a finalized timeline will be issued in March.

### **IPAC-RS PDS Profile Comparison Working Group Status**

David Christopher reported that his group is in the process of developing a work plan. The objective is to develop a robust statistical method for assessing equivalence based on PSD. This plan will deal with aerosols only.

The next DPTC meeting is scheduled for Thursday, April 25, 2002 at 10:00 a.m. at the FDA – Woodmont 2 building in Rockville, Maryland.