Advisory Committee for Pharmaceutical Science
October 21 - 22, 2003

Day 1: Tuesday October, 2003

Draft PAT Guidance – Update

CDER Guidance for Industry. PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance. Draft Guidance. August 2003.

Parametric Tolerance Interval Test for Dose Content Uniformity

1. The Parametric Tolerance Interval Test (PTIT). Wallace Adams. September 22, 2003.

2. IPAC-RS. A Parametric Tolerance Interval Test for Improved Control of Delivered Dose Uniformity of Orally Inhaled and Nasal Drug Products. November 15, 2001. Final Updated September 2002.

3. IPAC-RS Summary pages
   - Pharmaceutical product quality assurance through CMC drug development process. Darlene Rosario. September 22, 2003

   - Summary of IPAC-RS proposal for improved control of delivered dose uniformity (DDU) of orally inhaled and nasal drug products (OINDP). Michael Golden. September 22, 2003.

   - Zero tolerance criteria do not assure product quality. John R. Murphy. September 23, 2003.

Day 2: Wednesday October 22, 2003

Risk-based CMC Review Proposals

1. FDA Advisory Committee for Pharmaceutical Science Manufacturing Subcommittee Meeting September 17, 2003. Rockville MD.

   - Woodcock, Janet. Defining quality of a pharmaceutical product. Slides presented September 17, 2003.

   - Hussain, Ajaz. Quality by design: Next steps to realize opportunities? Slides presented September 17, 2003.

2. DIA Annual Conference. June 14 – 17, 2003. San Antonio, TX.

- Chiu, Yuan-Yuan. FDA GMP initiatives: Impact on CMC reviews/reviewers. Slides presented June 17, 2003.

- Sayeed, Vilayat. Risk-assessment drug product quality attributes. Slides presented June 17, 2003.

3. FDA Advisory Committee for Pharmaceutical Science Manufacturing Subcommittee Meeting May 21-22, 2003. Rockville MD.

- Bensley, Dennis. Changes without prior approval: An FDA perspective. Slides presented May 22, 2003.

- Claycamp, H. Gregg. A perspective on risk analysis for the GMP initiative. Slides presented May 22, 2003.

4. FDA/PQRI Public Workshop – A Drug Quality System for the 21st Century held April 22 – 24, 2003. Washington DC.

- Changes without Prior Approval. Slides presented by Rick Smith, Aventis Pasteur, Inc.

- Risk-Based cGMPs: Defining Risk and Quality. Summary of stakeholder comments

5. FDA Advisory Committee for Pharmaceutical Science transcript from October 21, 2002 pages 87 - 111. Topic – Updates. Risk-Based CMC Review.

- Sayeed, Vilayat. Update on risk-based CMC review. Slides presented at FDA Advisory Committee for Pharmaceutical Science October 21, 2002.

- Chiu, Yuan-Yuan. Risk based CMC review: An update. Slides. presented at FDA Advisory Committee for Pharmaceutical Science.

Nomenclature

1. Summary of topic and questions for committee. Moheb Nasr. September 23, 2003.

2. FDA Advisory Committee for Pharmaceutical Science transcript from March 12 – 13, 2003. pages 61 - 149. Topic: Topical Dermatological Bioequivalence – Methods Development.

Research for Generics - Bioequivalence of Topical Products
Summary of topic and questions for the committee. Lawrence Yu. September 22, 2003.