

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Process Analytical Technologies Subcommittee of the
Advisory Committee for Pharmaceutical Science**

Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD

June 12, 2002

AGENDA

- 8:30 Call to Order:** Thomas Layloff, Ph.D., Acting Chair
- 8:40 Meeting Statement:** Kathleen Reedy, RDH, MS, Executive Secretary (acting)
- 8:50 Introduction, Overview, Training and Objectives of Subcommittee**
Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science
- 9:35 Subcommittee Discussion on Training**
- 10:20 Break**
- 10:35 Regulatory Challenges:**
PAT Applications in NDAs : Jeffrey Blumenstein, Ph.D., Pfizer Inc.
PAT Application in ANDAs: Steven Bende
PAT Application Post-Approval: Dhiren N. Shah, Ph.D., Aventis Pharmaceuticals
PAT Validation/GMP issues: Henry Avallone, B.Sc., Johnson & Johnson
- 11:30 Subcommittee Discussion on Regulatory Risk**
- 12:00 Lunch**
- 1:00 Open Public Hearing:**
Justin O. Neway, Ph.D: Aegis Analytical Corporation
Li Peckan, Allan Wilson: The 2080 Group
Dan Klevisha, Tom Tague, Ph.D., Jon Goode, Ph.D: Bruker Optics
- 2:00 Subcommittee Discussion on Regulatory Risks and Training**
- 3:00 Break**
- 3:15 Subcommittee Discussion**
- 4:30 Working Group Sessions and Strategy**
- 5:00 Adjourn**

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June 13, 2002

AGENDA

- 8:00 Call to Order:** Thomas Layloff, Ph.D., Acting Chair
- 8:10 Meeting Statement:** Kathleen Reedy, RDH, MS, Executive Secretary (acting)
- 8:15 Charge to Working Groups:** Thomas Layloff, Ph.D., Acting Chair
- 8:30 Working Group Discussions**
- 10:00 Break**
- 10:15 Working Group Discussions**
- 11:15 Consensus and Summary Preparation**
- 12:00 Lunch**
- 1:00 Open Public Hearing**
- Working Group Summaries:**
- 1:30 Product and Process Development:** Judy P. Boehlert, Ph.D., Chair
- 1:45 Subcommittee Question and Answers**
- 2:15 Process and Analytical Validation:** Arthur H. Kibbe, Ph.D., Chair
- 2:30 Subcommittee Question and Answers**
- 3:00 Break**
- 3:15 Subcommittee Discussion**
- 4:15 Summary:** Ajaz Hussain, Ph.D., Deputy Director,
Office of Pharmaceutical Science
- 4:25 Closing Remarks:** Thomas Layloff, Ph.D., Acting Chair
- 4:30 Adjourn**