Advisory Committee for Pharmaceutical Science
Manufacturing Subcommittee
September 17, 2003

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1. ICH Concept Paper: Proposal for the preparation of a quality guideline on pharmaceutical development. August 17, 2003.

2. ICH Conclusions from Informal Discussion Group – GMP: New proposal for the development of an ICH Guideline on GMP related issues. July 18, 2003

3. CDER Guidance for Industry. Drug Product. Chemistry, Manufacturing, and Controls Information. Draft Guidance. January 2003.

4. CDER Guidance for Industry. PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance. Draft Guidance. (Will be provided when available to the public)

5. FDA Advisory Committee for Pharmaceutical Science transcript from July 19, 2001 pages 125 – 172. Topic – Chemistry, Manufacturing and Controls Introduction and Overview of Proposal.

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

7. FDA/PQRI Public Workshop – A Drug Quality System for the 21st Century held in Washington DC April 22 – 24, 2003.
   - Changes without Prior Approval – Rick Smith, Aventis Pasteur, Inc.
   - Integrating CMC Review and Inspection Industry Recommendations – Joe Anisko.
   - Risk-Based cGMPs: Defining Risk and Quality. Summary of stakeholder comments.
   - PQRI / FDA Workshop Manufacturing Science Workshop Report. June 16, 2003.