NICEATM Draft 26 Jan 2007

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)

Independent Scientific Peer Review: Five *In Vitro* Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products

NIH Campus, Natcher Conference Center Bethesda, MD Conference Room E1/E2

Tuesday, February 6, 2007 8:30 a.m. – 5:00 p.m.

1. Opening Session

- Call to Order and Panel Introductions
- Welcome and Overview of the ICCVAM Test Method Evaluation Process, Charge to the Panel, and Conflict of Interest Statement
- Overview of Pyrogenicity Testing Requirements and Current Pyrogenicity Testing Procedures Methods
- Overview of the DRAFT *In Vitro* Pyrogenicity Test Method Background Review Document (BRD)

2. Peer Review of the BRD for Completeness, Errors, and Omissions

- Panel Discussion
- Public Comments
- Panel Conclusions and Recommendations

3. Validation Status of Proposed Methods

- Panel Discussion
- Public Comments
- Panel Conclusions and Recommendations

4. Draft ICCVAM Recommendations for In Vitro Pyrogenicity Test Methods

- Panel Discussion
- Public Comments
- Final Panel Conclusions and Recommendations