

Independent Scientific Peer Review Panel Meeting

Evaluation of the an *In Vitro* Estrogen Receptor (ER) Transcriptional Activation (TA) Test Method for Endocrine Disruptor Chemical Screening

NIH Campus, Natcher Conference Center
45 Center Drive
Bethesda, MD 20892

Tuesday, March 29, 2011 – Wednesday, March 30, 2011

TENTATIVE Agenda and Order of Business*

Tuesday, March 29, 2011*

8:30 a.m. Opening session

Call to Order and Panel Introductions
Welcome
Overview of ICCVAM Evaluation
Evaluation Process and Charge to the Panel
Conflict of Interest Statements
Overview of Agenda

The BG1Luc ER TA Test Method

Staff Presentation: Overview of the BG1Luc ER TA Test Method (LUMI-CELL[®] ER TA), Validation Results, and Draft ICCVAM Recommendations

Panel Discussions of BRD:

- Section 1 (Introduction)
- Section 2 (Test Method Protocol)
- Section 3 (Reference Substances)
- Section 4 (Data and Results)
- Section 5 (Test Method Accuracy)
- Section 7 (Data Quality)

Public Comments

Additional Panel Discussions

5:00 p.m. Adjourn for the Day

* **Note:** *This is a tentative schedule. The actual agenda may vary and it is possible that the panel may progress to the next topic earlier than scheduled, even if listed for the following day.*

Wednesday, March 30, 2011*

8:30 a.m. Call to Order and Introductions

The BG1Luc ER TA Test Method

Panel Discussions of BRD:

- Section 6 (Test Method Reliability)
- Section 8 (Other Studies)
- Section 9 (Animal Welfare)
- Section 10 (Practical Considerations)

Public Comments

Additional Panel Discussions

Action: Panel Conclusions and Recommendations

Staff Presentation: Overview of the Draft ICCVAM BG1Luc ER TA Test Method Recommendations on Usefulness, Limitations, and Future Studies

Panel Discussions: Draft ICCVAM Recommendations

Public Comments

Additional Panel Discussions

Action: Panel Conclusions and Recommendations

Staff Presentation: Overview of the Draft ICCVAM BG1Luc ER TA Test Method Performance Standards

- Essential Test Method Components
- Recommended Reference Substances
- Test Method Performance Criteria

Panel Discussions: Draft ICCVAM Performance Standards

Public Comments

Additional Panel Discussions

Action: Panel Conclusions and Recommendations

5:00 p.m. Adjourn for the Day

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