

APPENDIX C

Expert Panel Evaluation Meeting Agenda

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**Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
Expert Panel Evaluation of the Validation Status of
In Vitro Test Methods for Detecting Endocrine Disruptors:**

Estrogen Receptor and Androgen Receptor Binding
and Transcriptional Activation Assays

Agenda

Meeting Venue: Sheraton Imperial Hotel, Imperial Ballroom
Research Triangle Park, North Carolina

Date: May 21-22, 2002

Objectives for the Expert Panel:

The Panel is charged with reviewing the information and data provided in the Background Review Documents (BRDs) and developing conclusions and recommendations on the following:

1. *In vitro* estrogen receptor (ER)/androgen receptor (AR) binding and transcriptional activation (TA) assays that should be considered for further evaluation in validation studies, and their relative priority for further evaluation.
2. The adequacy of the minimum procedural standards recommended for *in vitro* ER/AR binding and TA assays.
3. The adequacy of available *in vitro* ER/AR binding and TA test method protocols for use in validation studies.
4. The adequacy and appropriateness of substances recommended for validation studies of *in vitro* ER/AR binding and TA assays.

**ICCVAM Endocrine Disruptor Expert Panel Public Meeting
Sheraton Imperial Hotel
Research Triangle Park, NC
Imperial Ballroom**

Tuesday, May 21, 2002

8:30 a.m. Opening Session

1. Call to Order and Panel Introductions (*Panel Chair, Dr. George Daston*)
2. Overview of the ICCVAM Test Method Evaluation Process and Charge to the Panel (*Dr. William Stokes*)
3. Overview of ER and AR *In Vitro* Binding and Transcriptional Activation Assays (*Dr. Vickie Wilson*)

9:05 a.m. ER Binding Assays: Evaluation of the ER Binding Background Review Document
(*Drs. Daston, Ben-Jonathan, Combes, Giesy, Harbell, Safe, Wittliff, and Piegorsch*)

Overview of the ER Binding Background Review Document

Question #1: Recommendations and Priority for Validation Studies
PANEL DISCUSSION OF QUESTION #1

Question #2: Minimum Procedural Standards for *In Vitro* ER Binding Assays
PANEL DISCUSSION OF QUESTION #2

10:30 a.m. Break

10:45 a.m. ER Binding Assays (Continued)

Question #3: Recommendations for *In Vitro* ER Binding Protocols for Validation Studies
PANEL DISCUSSION OF QUESTION #3

Question #4: Recommended List of Substances to be used for Validation of *In Vitro*
ER Binding Assays
PANEL DISCUSSION OF QUESTION #4

12:05 p.m. Public Comment

12:30 p.m. Lunch Break

1:30 p.m. ER TA Assays: Evaluation of the ER TA Background Review Document
(Drs. Stegeman, Charles, Mihaich, Wiese, Yager, Zacharewski, and Peddada)

Overview of the ER TA Background Review Document

Question #1: Recommendations and Priority for Validation Studies
PANEL DISCUSSION OF QUESTION #1

Question #2: Minimum Procedural Standards for *In Vitro* ER TA Assays
PANEL DISCUSSION OF QUESTION #2

2:55 p.m. Break

3:10 p.m. ER TA Assays (Continued)

Question #3: Recommendations for *In Vitro* ER TA Protocols for Validation Studies
PANEL DISCUSSION OF QUESTION #3

Question #4: Recommended List of Substances to be used for Validation of *In Vitro*
ER TA Assays
PANEL DISCUSSION OF QUESTION #4

4:30 p.m. Public Comment

5:00 p.m. Adjourn for the day

Wednesday, May 22, 2002

8:30 a.m. AR Binding Assays: Evaluation of the AR Binding Background Review Document
(Drs. Brown, Gasiewicz, Inoue, Robaire, Vinggaard, and Piegorsch)

Overview of the AR Binding Background Review Document

Question #1: Recommendations and Priority for Validation Studies
PANEL DISCUSSION OF QUESTION #1

Question #2: Minimum Procedural Standards for *In Vitro* AR Binding Assays
PANEL DISCUSSION OF QUESTION #2

9:55 a.m. Break

10:10 a.m. AR Binding Assays (Continued)

Question #3: Recommendations for *In Vitro* AR Binding Protocols for Validation Studies
PANEL DISCUSSION OF QUESTION #3

Question #4: Recommended List of Substances to be used for Validation of *In Vitro* ER Binding Assays
PANEL DISCUSSION OF QUESTION #4

11:30 p.m. Public Comment

12:00 p.m. Lunch Break

1:00 p.m. AR TA Assays: Evaluation of the AR TA Background Review Document
(Drs. Wilson, Gaido, Kelce, and Peddada)

Overview of the AR TA Background Review Document

Question #1: Recommendations and Priority for Validation Studies
PANEL DISCUSSION OF QUESTION #1

Question #2: Minimum Procedural Standards for *In Vitro* AR TA Assays
PANEL DISCUSSION OF QUESTION #2

Question #3: Recommendations for *In Vitro* AR TA Protocols for Validation Studies
PANEL DISCUSSION OF QUESTION #3

3:05 p.m. Break

3:20 p.m. **AR TA Assays** (*Continued*)

Question #4: Recommended List of Substances to be used for Validation of *In Vitro*
AR TA Assays
PANEL DISCUSSION OF QUESTION #4

4:00 p.m. **Closing Comments**

5:00 p.m. **Adjourn**

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