

Uterotrophic Assay Post Peer Review Options

December 2, 2005

1. Agree with members of the Peer Review Panel who believe that the uterotrophic assay has been adequately validated for the detection of estrogen agonists.
 - Data generated in OECD validation program demonstrated the ability to detect weak to strong estrogens.
 - Limitations of uterotrophic assay were defined in BRD (progestins and androgens give false positive responses) but there is a low likelihood of other interference.
 - No additional negative data need to be considered.
 - Protocol issues identified by the Panel are relatively minor and can be addressed now, but probably would not materially affect the development of a test guideline.

2. There is a need for more negative data to adequately assess the assay, but negative data from studies in a single lab using the OECD protocol could meet this need.
 - Unpublished data on 6 negative chemicals have been generated by CERI using the OECD protocol but were not available to the Peer Review Panel.
 - Path forward: Obtain permission to use these data and submit the data to a new peer review panel to reevaluate the validation status of the assay.

3. More negative data are required across multiple laboratories.

- Data on 2 additional negative chemicals would be generated in 3 laboratories
- Validation data package would be resubmitted to a new peer review panel
- Will entail a 1 year delay in determining validation status and regulatory acceptance
- Test Guideline not ready until late 2007 or 2008