Wrap Up of Day 1
Looking Forward to Day 2

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Day 1

- Background and context for PQRI L&E effort
- Threshold of toxicological concern
- Development and justification of safety concern and qualification thresholds for leachables and extractables in OINDP

Day 2

- Explanation of best practices for L&E studies in the OINDP pharmaceutical development process, including description and application of the analytical evaluation threshold (AET)
- Perspectives from FDA participants in the L&E Working Group

Day 2

- Open discussion/Q&A with L&E Working Group members
- Presentation from Helen Winkle

Discussion

- Please
  - Continue to ask questions and contribute your comments
  - Feel free to speak individually with working group members
- We look forward to seeing you at the poster session and reception tonight and at the Workshop tomorrow