Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
Department of Health and Human Services

Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2020 Generic Drug Research
Public Workshop

Panel Members

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Session I: Implementation of FY 19 Generic Drug Research Priorities
Subtopic 1: The Value to the Generic Industry in Expanding BCS Class 3 Waivers to Non-Q1/Q2 Formulations

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Subtopic 2: Scientific Gaps that Impact the Prediction of the Results of Fed BE Studies

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Subtopic 3: Challenges for Industry in Implementing New Analytical/Computational Methods that Arise from Regulatory Science Initiatives

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Session II: New Drug Approvals that Pose Scientific Challenges to Generic Product Development

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Session III: Considerations for Future Regulatory Science Initiatives

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