FY 2019 GDUFA Regulatory Science Initiatives Public Workshop

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Goals for the Workshop

- Opportunity for public input on research priorities
  - At the meeting
  - Via the public docket FDA-2017-N-6644
  - See FR notice for a confidential comment process

Format

- Two panels with FDA, industry and public presentation followed by open discussion
- Morning panel seeks input on the FY 2019 regulatory science initiatives
  - Focus on BCS, Fed BE and implementation of new methods
- Afternoon panel seeks input on potential new regulatory science initiatives
  - Review of recently approved NDAs

Impact of GDUFA Research

- FDA's research on complex generics helps the development of more generic competition in areas where bioequivalence evaluation is scientifically challenging
- FDA's research helps to make generic drug development and review more efficient

Save the Date

- CDER Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI)
  - Complex Generic Product Development Workshop
  - Sept. 25-26, 2018 (THE HOTEL, College Park, MD)
- This workshop will give a deep dive into the complex generic drug development process and with a focus on linking GDUFA science and research for complex products to Pre-ANDA meetings and product-specific guidance development.


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