

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, 2019 (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.

