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Welcome!



FDA's GDUFA Science and Research Program in 2019

- Funded approx. \$20 million in research
 - 14 new contracts
 - 3 new grants
 - 23 contracts
 - 2 ongoing grants to conduct scientific research
- 57 ongoing external research collaborations

New Web Page: GDUFA Science and Research Outcomes



The screenshot shows the FDA website header with the logo and navigation links. The main heading is "FY 2018 GDUFA Science and Research Outcomes". Below the heading are social media sharing options for Facebook, Twitter, LinkedIn, Email, and Print. The main content area contains two paragraphs: "Each year, FDA prepares annual reports on the science and research-funded projects conducted under the Generic Drug User Fee Amendments of 2017 (GDUFA II) regulatory science program. These reports provide greater transparency regarding the important work the Agency engages in to advance the science of generic drugs and provide generic drug developers, applicants, and FDA reviewers essential tools and information to help expedite the availability of high-quality, lower-cost safe and effective generic drugs." and "The agency is committed to reporting on research outcomes (or results) from projects that...". On the left side, there is a sidebar with a "Generic Drugs" section containing links for "Overview & Basics", "Industry Resources", and "Approvals & Reports". On the right side, there is a "Content current as of: 09/20/2019" section, a "Regulated Product(s)" section listing "Drugs" and "Generic Drugs", and a "Topic(s)" section listing "User Fees".

This web page lists:

- pre-ANDA meetings,
- ANDA submissions,
- ANDA approvals,
- Product-Specific Guidances (PSGs), and
- Controlled Correspondences that were impacted by research, and more

Research Highlight



Physiologically-based pharmacokinetic modeling supported approval of a locally acting drug based on an efficient alternative bioequivalence approach.

New Features in Today's Workshop

Industry Leaders' Roundtable

Breakout Sessions:

- Post-Market Surveillance of Generic Drugs
- Drug-Device Combination Products
- In Vitro Bioequivalence Methods
- Data Analysis and Model-Based Bioequivalence

This year's workshop introduces two exciting new opportunities:



Industry Leaders' Roundtable!

Join us for a discussion with industry leaders about the current landscape of FDA's research program, and their perspective on various topics related to generic drug development.



Breakout Sessions! There will be four concurrent breakout sessions on various topics of interest.

