U.S. FOOD & DRUG ADMINISTRATION

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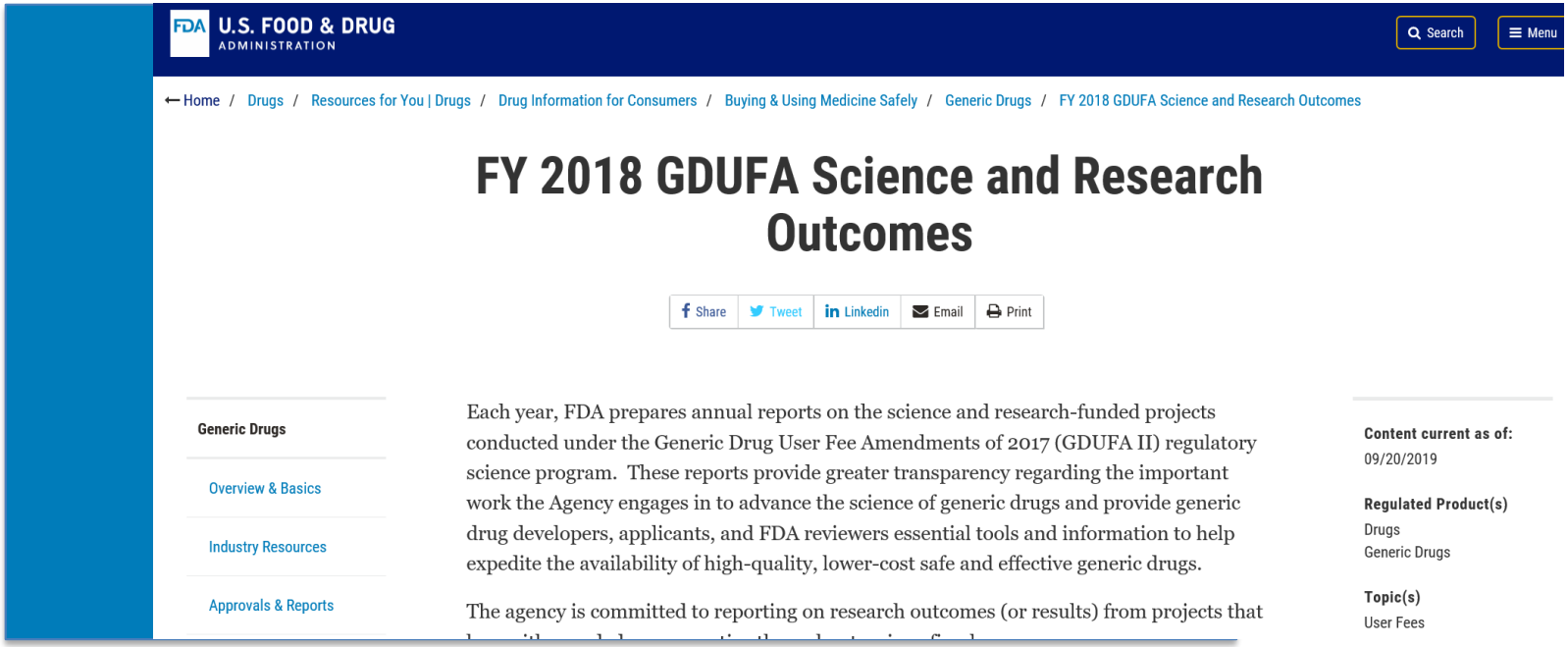
Welcome!

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

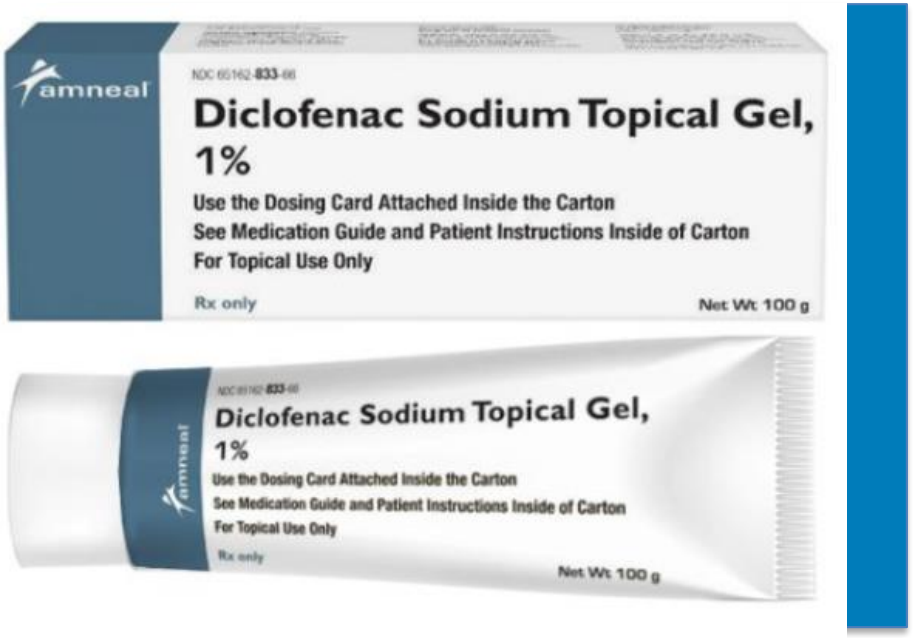
New Web Page: GDUFA Science and Research Outcomes



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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