FDA Sponsored Drug Research Towards Generics for Dermatology

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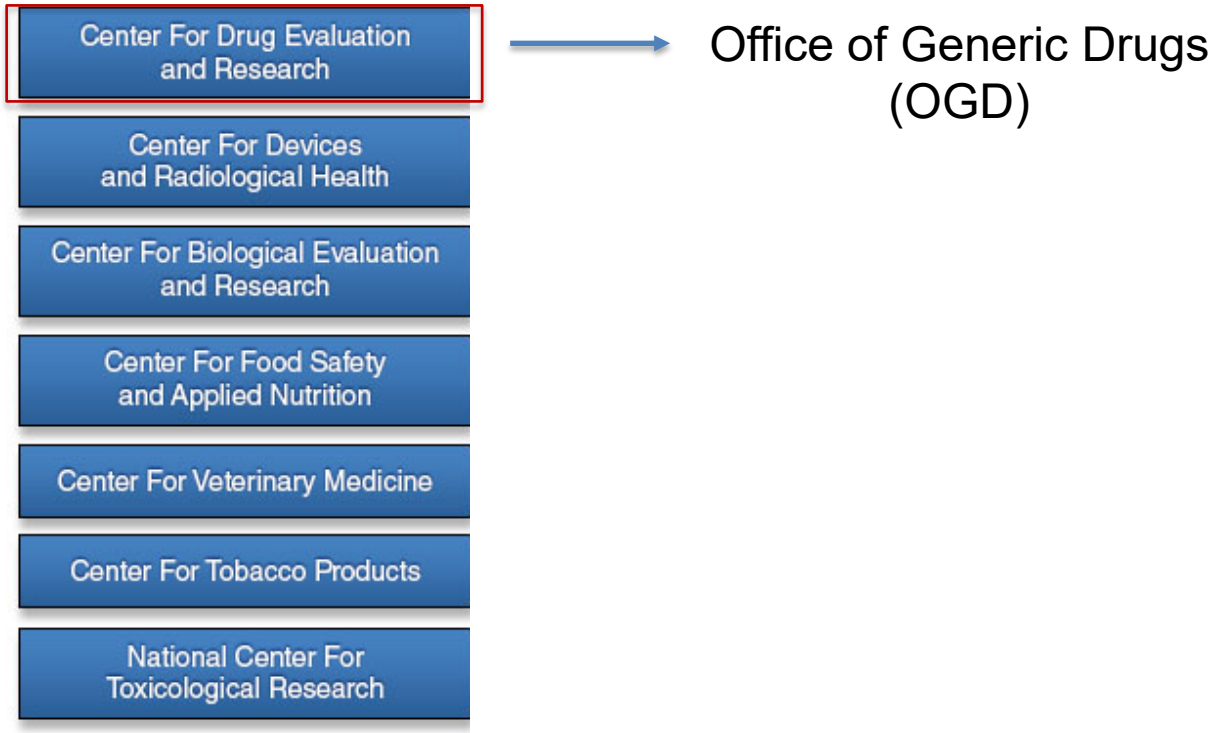
Disclaimer

This presentation reflects the views of the presenter and should not be construed to represent FDA's official views or policies.

FDA Organizational Structure



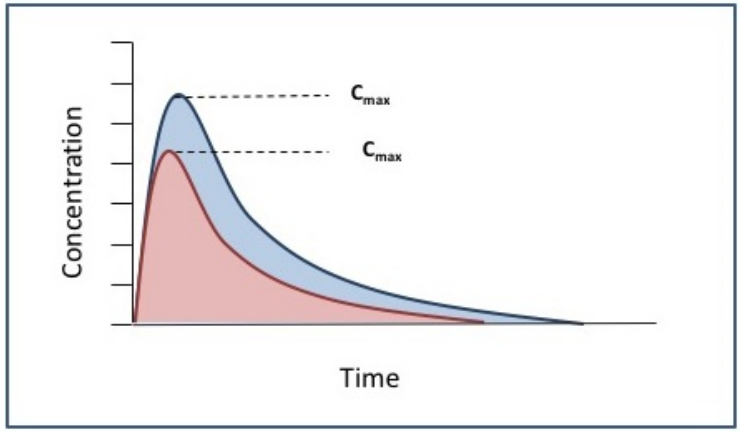
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-generic-drugs

The Promise of Generic Drugs

- Generic drug products use the same active ingredient(s) and can be expected to have the same clinical effect and safety profile when administered under conditions specified in the labeling, as the brand-name (reference) listed drug products
- Generic drug products can be substituted for the reference listed drug product
- ….And they can cost less money

https://www.fda.gov/drugs/generic-drugs/generic-drug-facts

How are Generic Drugs Approved?



Bioavailability (BA) is assessed, and bioequivalence (BE) is typically established by showing that a generic drug product and the reference standard are similar in terms of their concentrations over time at the site of action (e.g., in the blood)

https://www.fda.gov/drugs/regulatory-science-action/impact-story-developing-new-ways-evaluate-bioequivalence-topical-drugs

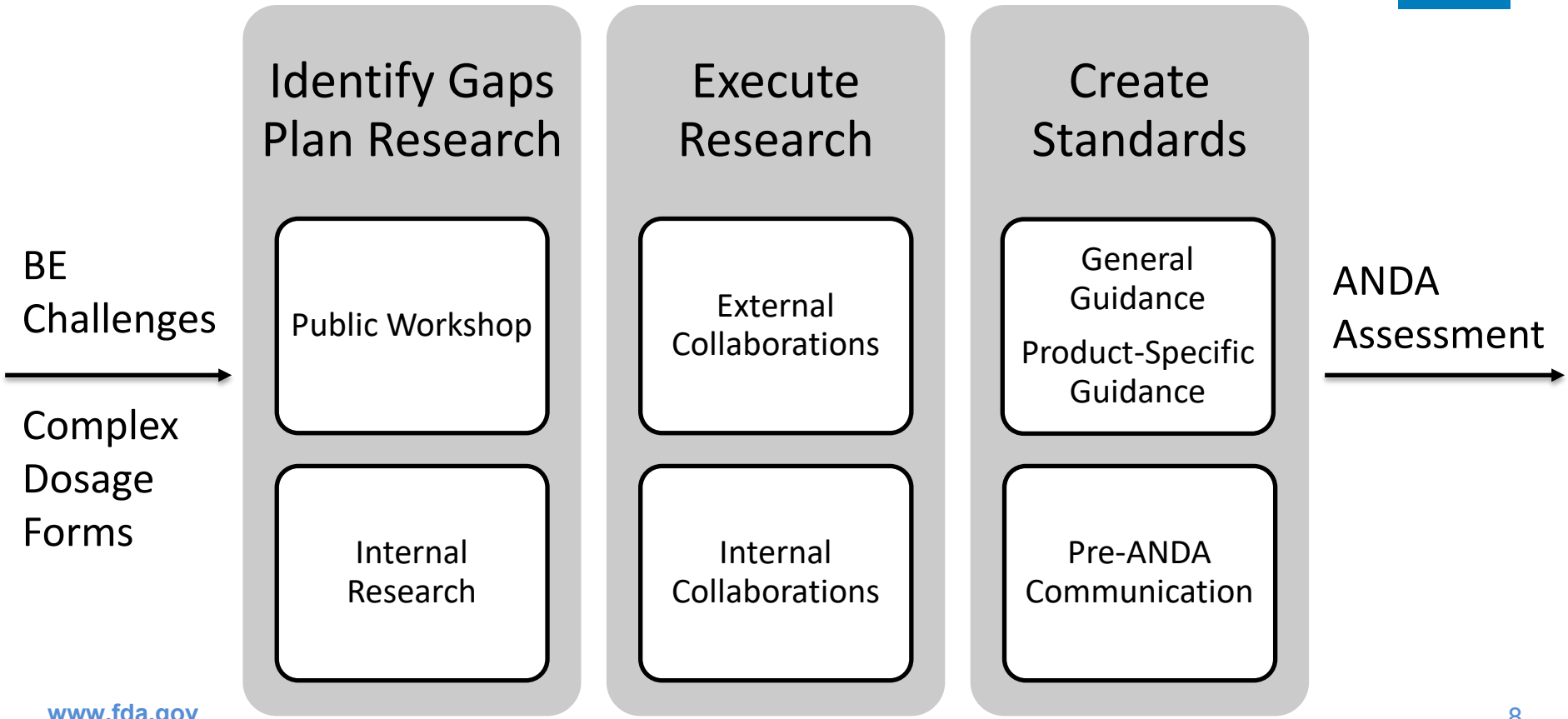
“Complex” Locally Acting Drug Products

GDUFA

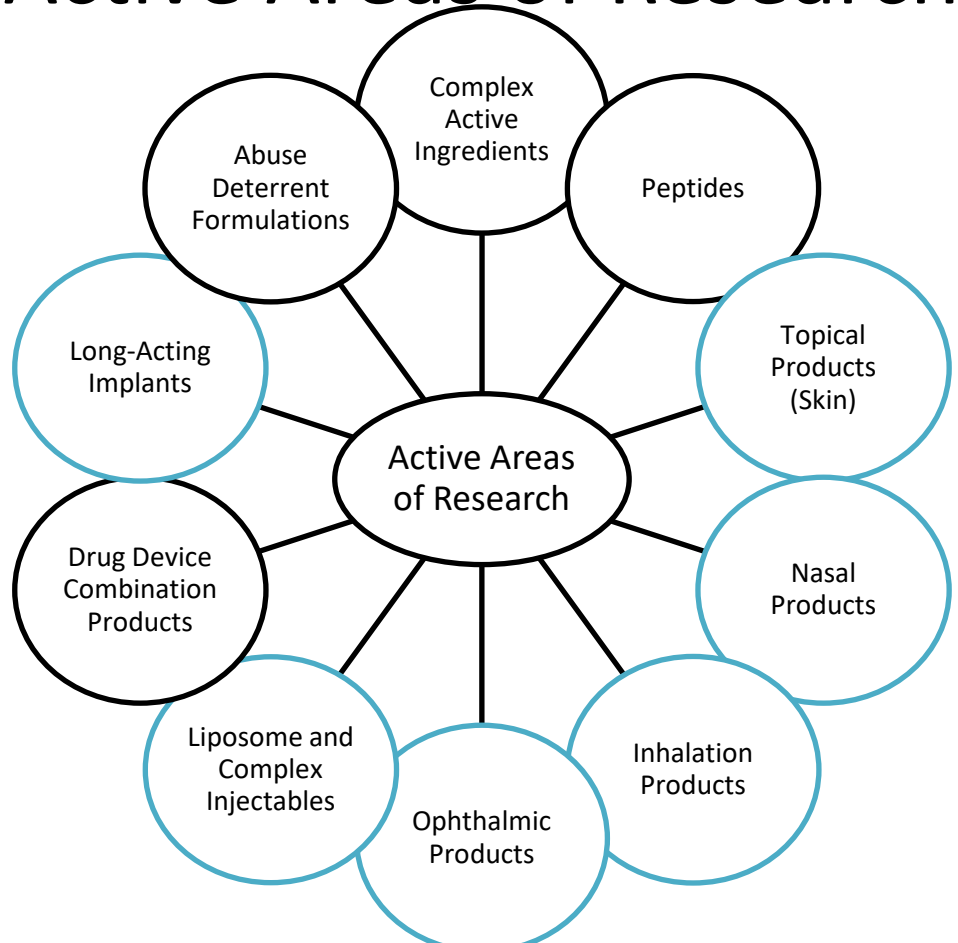
- The Generic Drug User Fee Amendments (GDUFA) was signed into law in July 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA)
- One out of numerous User Fee Programs that help the FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry
- GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and improve upon the predictability of the review process
- One unique feature of GDUFA is the Regulatory Science and Research Program ~ $20 million annually
- GDUFA must be reauthorized every 5 years (currently in GDUFA III)

https://www.fda.gov/industry/fda-user-fee-programs
https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments

GDUFA Science and Research Program



Active Areas of Research



Cutaneous Pharmacokinetics (PK)

- Microdialysis (dMD) and Open Flow Microperfusion (dOFM) directly measure the in vivo rate and extent of drug BA at/near the site of action in the skin

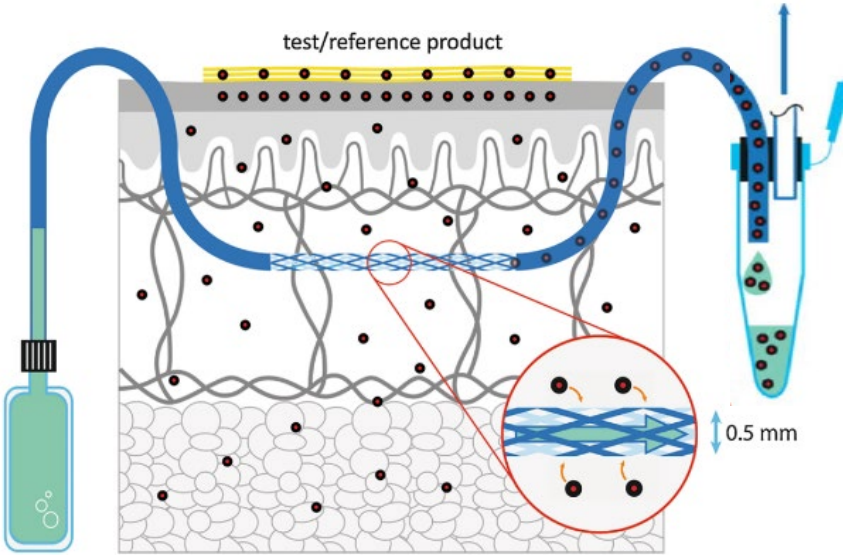
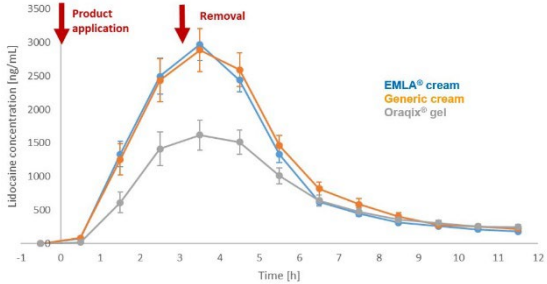
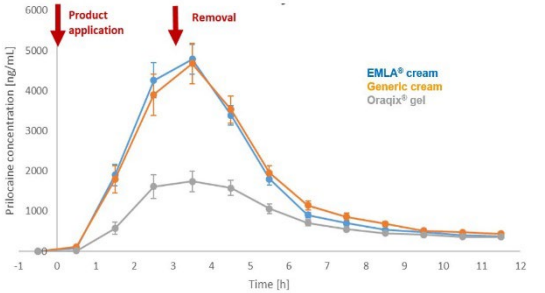


Image provided courtesy of Dr. Frank Sinner, Joanneum Research

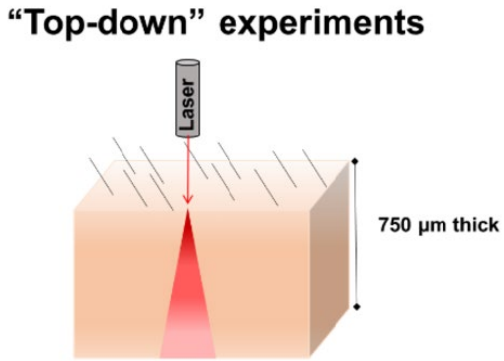


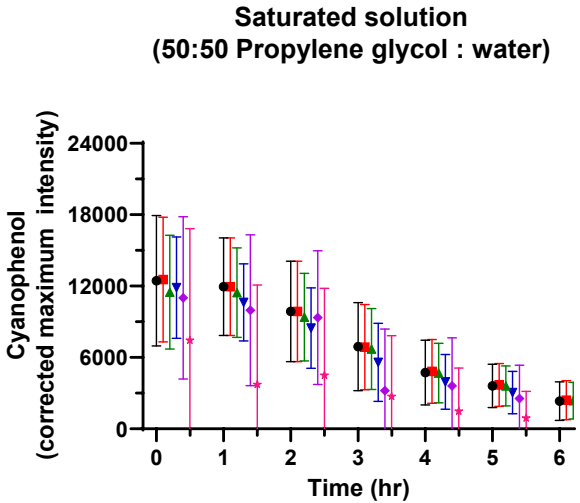


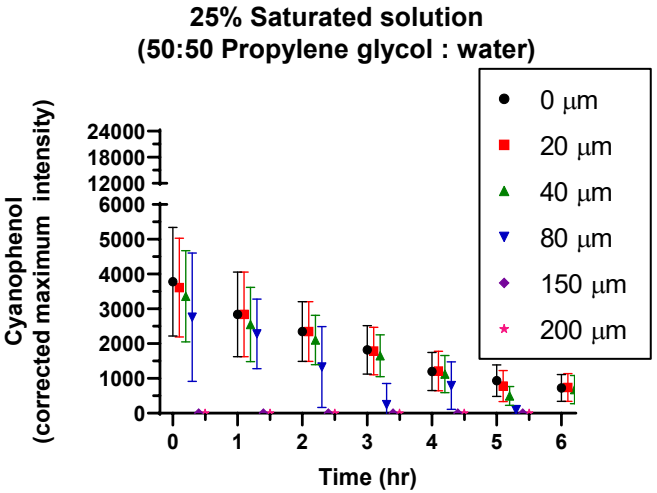
Dr. Frank Sinner provided with FDA funding for award U01-FD005861

Cutaneous PK

Confocal and Simulated Raman Spectroscopy can directly measure the rate and extent of drug bioavailability at/near the site of action in the skin.



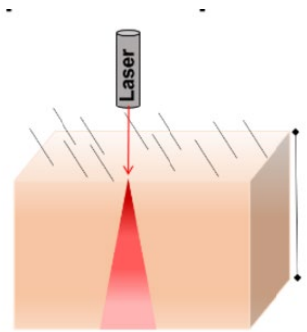


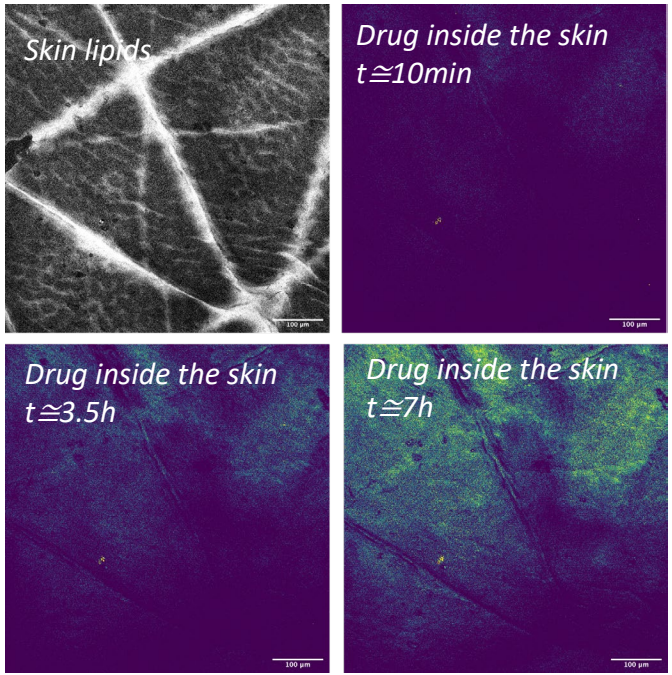


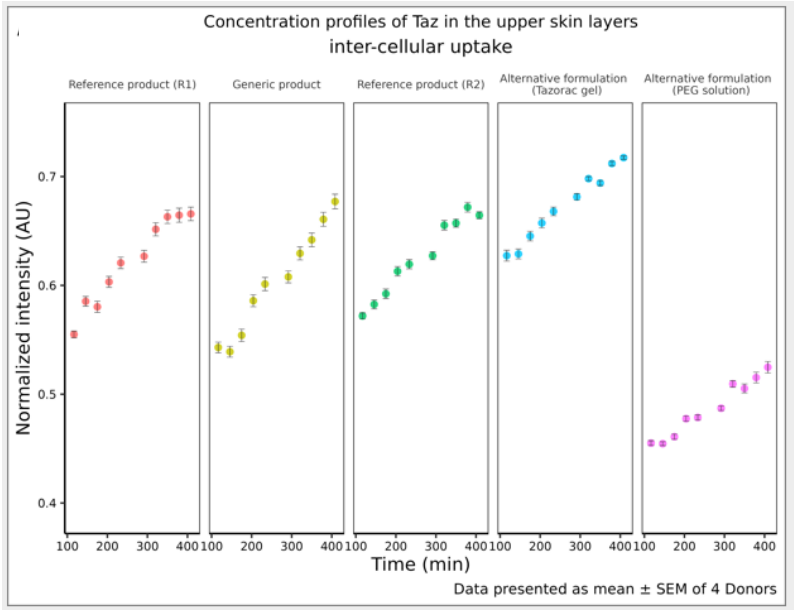
Dr. Richard Guy provided with FDA funding for award U01FD0006533

Cutaneous PK

Confocal and Simulated Raman Spectroscopy can directly measure the rate and extent of drug BA at/near the site of action in the skin.

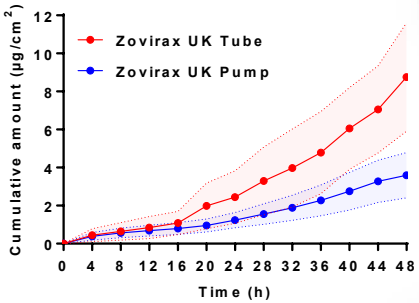






Dr. Conor Evans provided with FDA funding for award U01FD0006698

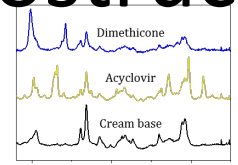
Understanding Product Microstructure

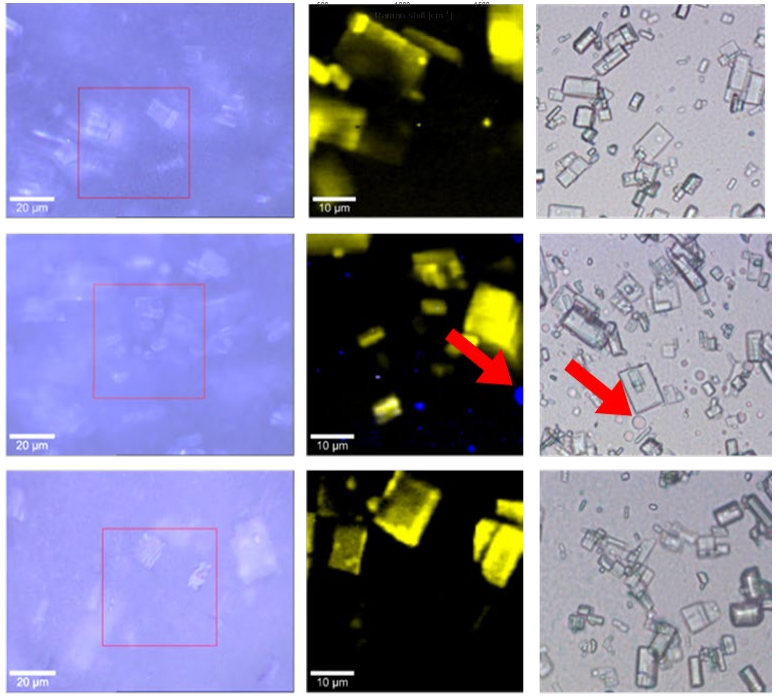


Zovirax® UK
Tube

Zovirax® UK
Pump

Zovirax® UK
Pump
(from inside container)

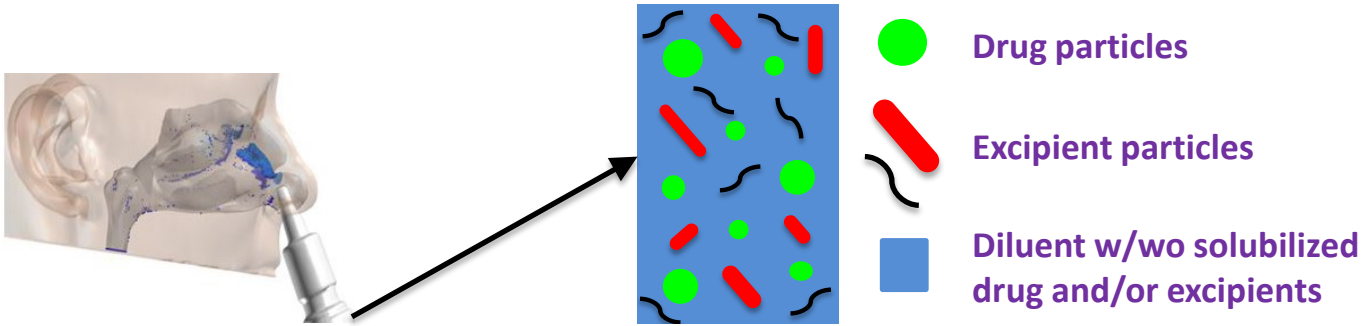




Prof. Michael Roberts provided with FDA funding for award U01-FD005226

Topical Drug Products (Skin)

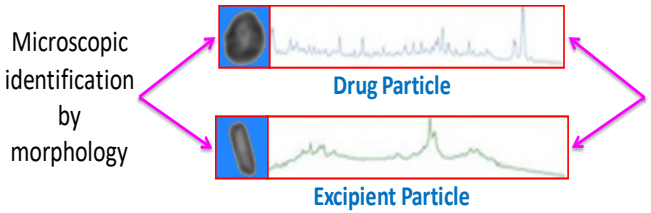
Nasal Suspension Sprays

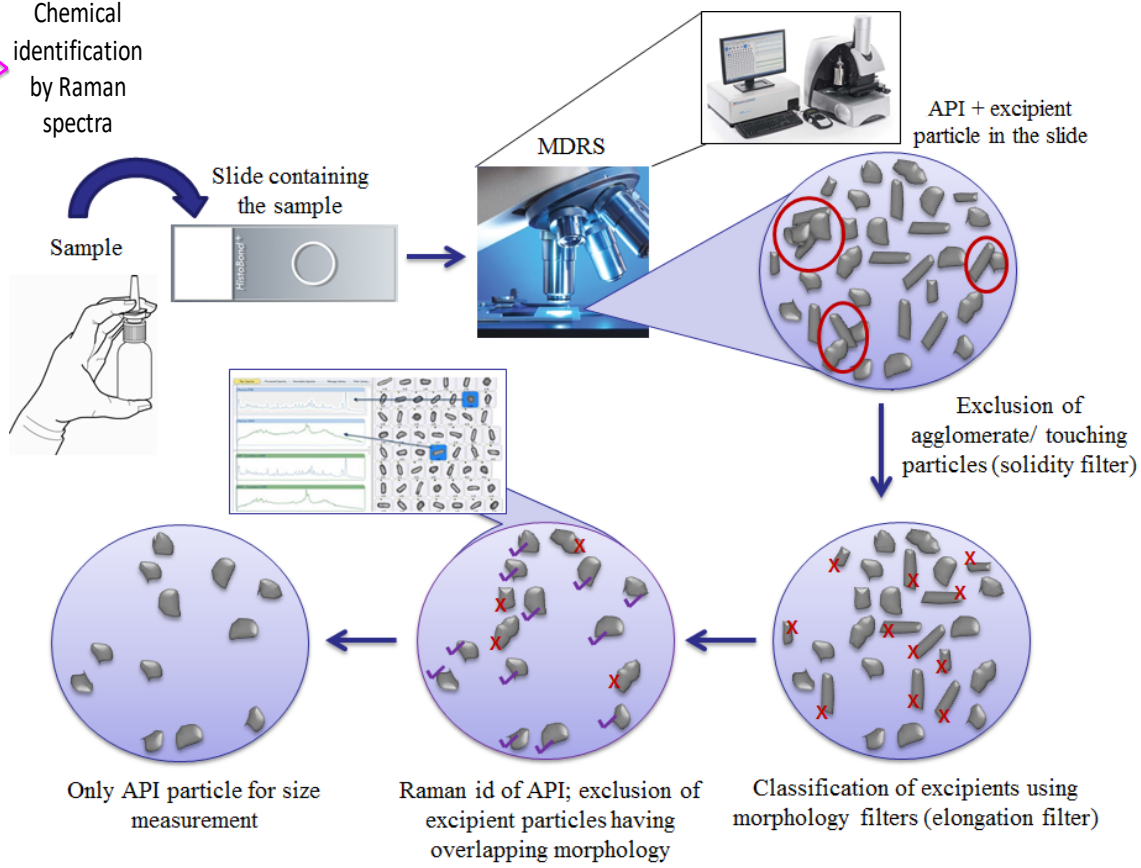


- Drug particle size distribution (PSD) in suspension formulations has the potential to influence the rate and extent of drug availability to nasal sites of action and systemic circulation
- Inability to adequately characterize drug PSD in aerosols and sprays using common analytical methods

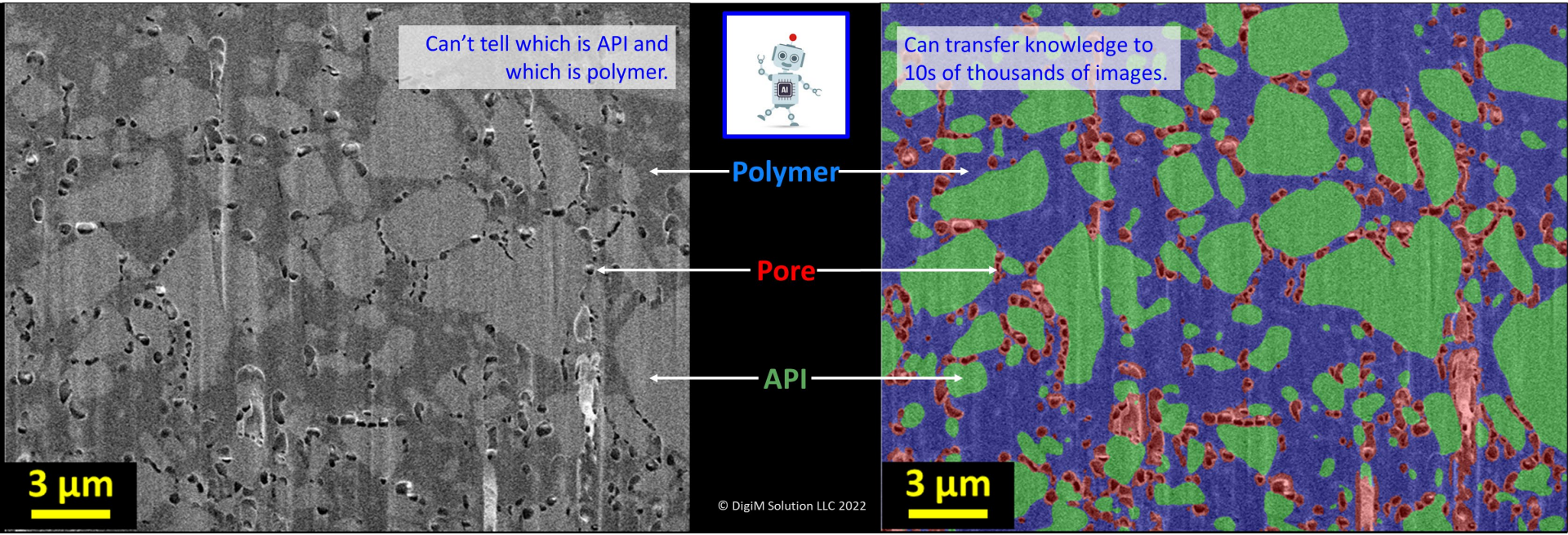
Orally Inhaled and Nasal Drug products (OINDP)

Morphologically-Directed Raman Spectroscopy





Imaging and Artificial Intelligence



Dr. Shawn Zhang (DigiM) provided with FDA funding for award Contract # 75F40119C10157

Ophthalmic/Complex Injectables/Long-Acting Drug Products

Summary

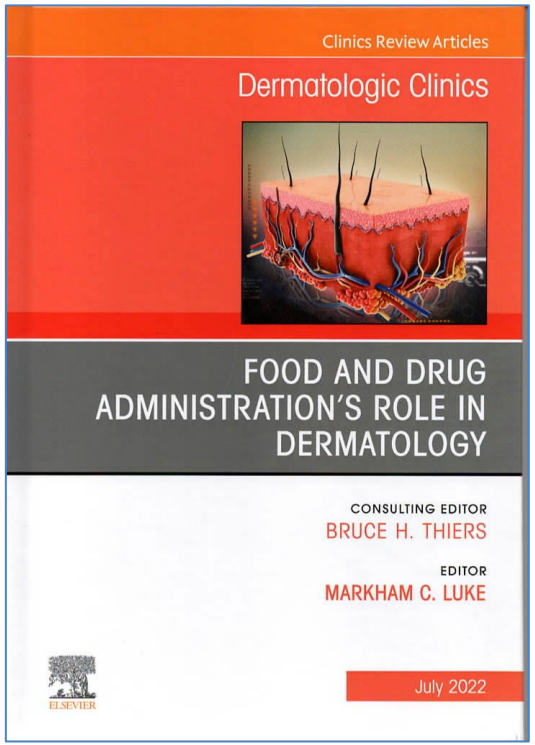
- The GDUFA regulatory science and research program is a model for research programs at the FDA
- The goal of the GDUFA regulatory science and research program is to facilitate the development of tools that can be utilized to facilitate drug development/establish BE and thereby enhance the availability of generic topical dermatological drug products
- Funding opportunities for relevant work

Quick References

- Research Priorities
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects
- Outcomes
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-publications-resources
- Collaborations
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-collaboration-opportunities

https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects

July 2022 Dermatologic Clinics

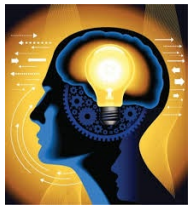


Insightful articles on:

- The History of Dermatology at FDA
- FDA and Dermatologic Drug Development
- Postmarket Assessment for Dermatology Drugs and Cutaneous Adverse Reactions
- How does FDA Approve Generic Drugs
- Dermatology Drugs for Children
- Regulation of Medical Devices for Dermatology
- Regulation of Cosmetics in the United States
- Cutaneous Pharmacokinetic Approaches
- Measuring What Matters to Patients in Dermatology Drugs

Partnering with the FDA

- Regulatory Science Extramural Research and Development Projects
  - FDA welcomes research proposals for Grants/ Contracts/ Etc.
  - Generic Drug Regulatory Science Initiatives Public Workshop, Summer, 2023
  - Postdoctoral Fellowship Opportunities- https://orise.orau.gov/fda/



https://www.fda.gov/drugs/generic-drugs/science-research

Acknowledgements

Office of Research and Standards

- Priyanka Ghosh, PhD
- Bryan Newman, PhD
- Yan Wang, PhD
- Katharine Feibus, MD
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- Lei Zhang, PhD
- Robert Lionberger, PhD

Research Collaborators

Collaborations within FDA

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Thank You

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