FDA Update: FDA and Dermatologic DEIA

American Dermatological Association Annual Meeting 2023
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Disclaimers

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

Any representation of brand name drugs in this talk are for purposes of scientific discussion and specific comparison.

FDA Centers

Most Relevant to Dermatology:

- **Center for Drug Evaluation and Research (CDER)**
  - Office of New Drugs (OND)
    - Division of Dermatology and Dental Drug Products
  - Office of Generic Drugs (OGD)
- **Center for Devices and Radiological Health (CDRH)**
- **Center for Biologics Evaluation and Research (CBER)**

  - Office of Cosmetics and Colors (now in Office of Chief Scientist) – 2023 reorganization of Foods

Dermatology Relevant FY2023 New Drugs

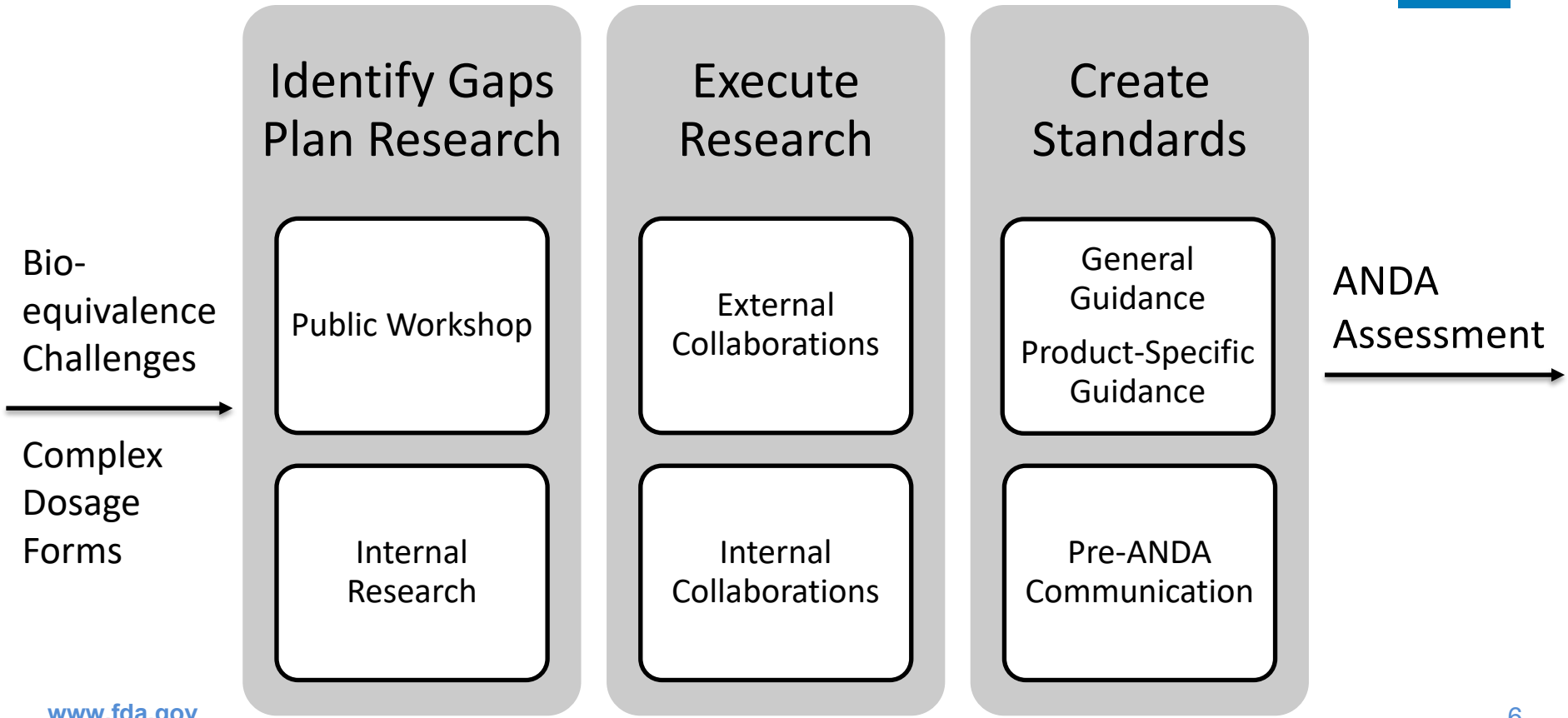
Drug Name	Active Ingredient	Approval Date	FDA-Approved Use
Xdemvy	lotilaner	7/25/2023	To treat Demodex blepharitis
Litfulo	ritlecitinib	6/23/2023	To treat severe patchy alopecia areata
Miebo	perfluorhexyloctane	5/18/2023	To treat signs and symptoms of dry eye disease
Elfabrio	pegunigalsidase alfa-iwxj	5/9/2023	To treat confirmed Fabry disease
Rezzayo	rezafungin	3/22/2023	To treat candidemia and invasive candidiasis
Zynyz	retifanlimab-dlwr	3/22/2023	To treat metastatic or recurrent locally advanced Merkel cell carcinoma
NexoBrid	anacaulase	12/28/2022	To remove eschar in adults with deep partial thickness or full thickness thermal burns

Over 10 years with 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)

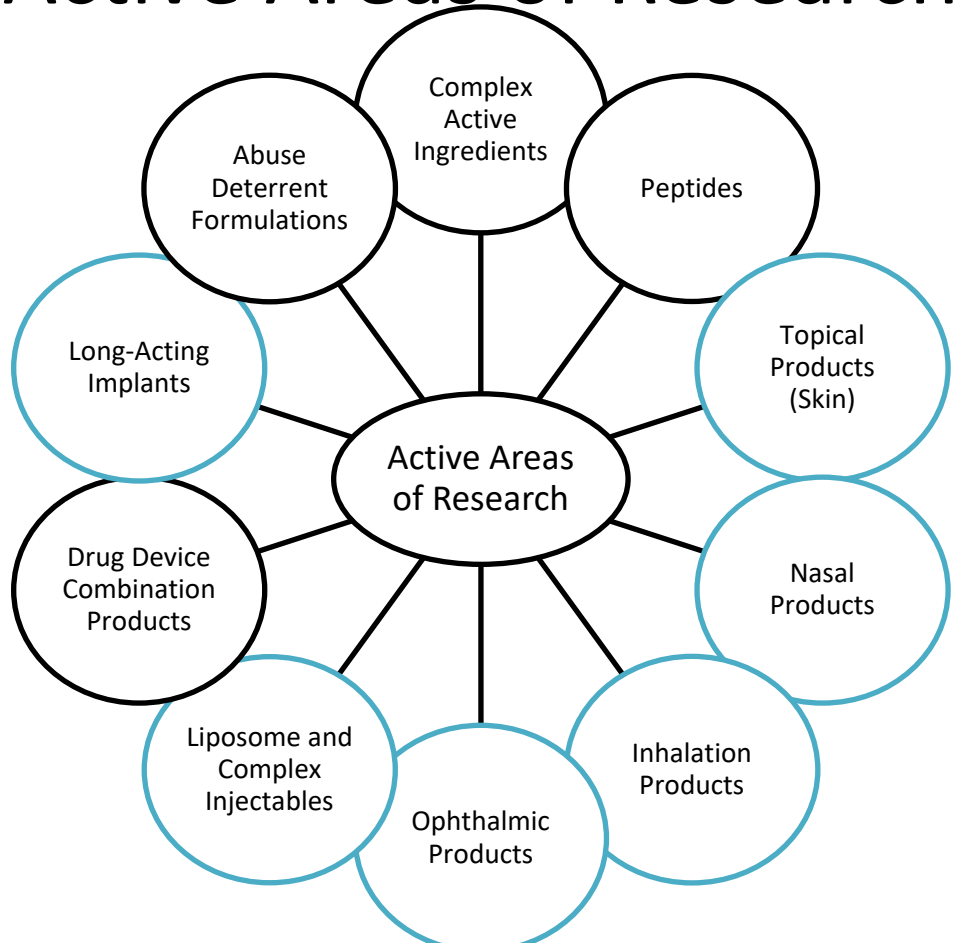
https://www.fda.gov/industry/fda-user-fee-programs
https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments

GDUFA Science and Research Program



BE: bioequivalence

Active Areas of Research



Cutaneous Pharmacokinetics (PK)

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

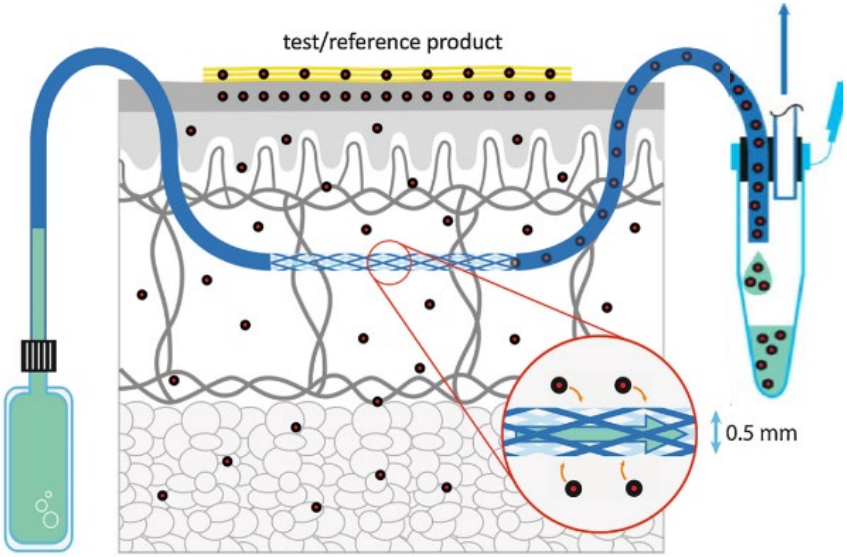
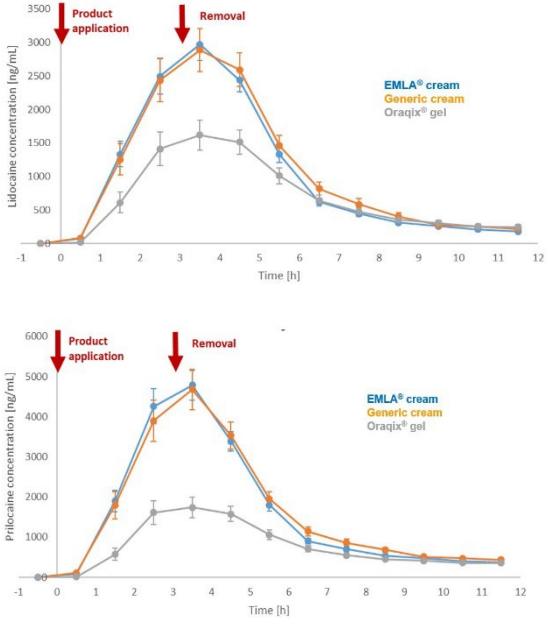


Image provided courtesy of Dr. Frank Sinner, Joanneum Research

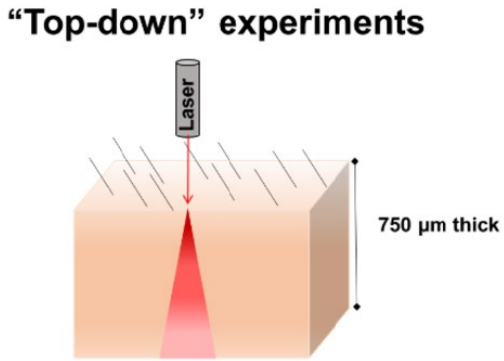


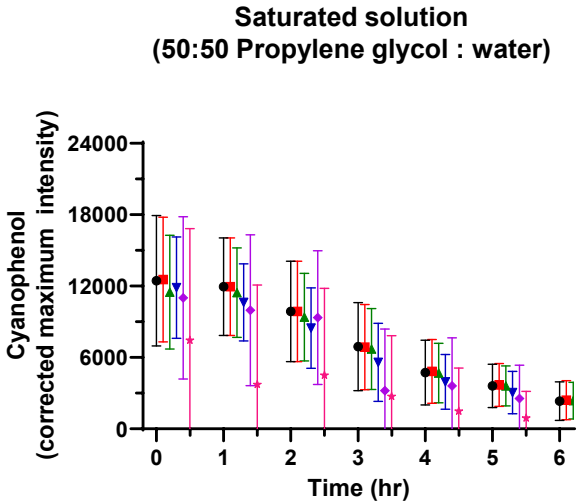
Dr. Frank Sinner provided with FDA funding for award U01-FD005861

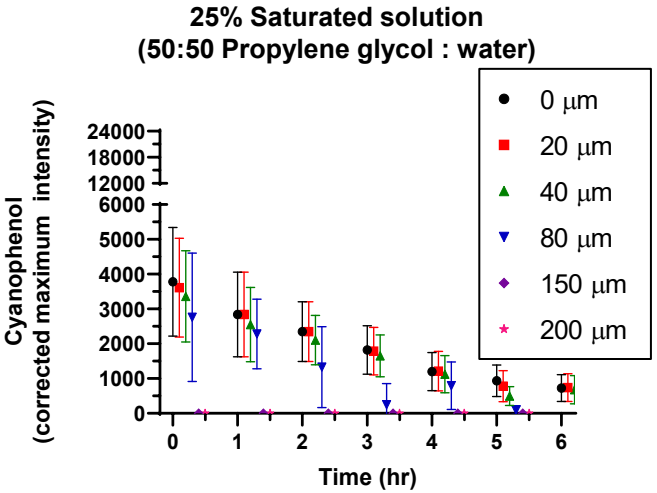
BA: bioavailability

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.



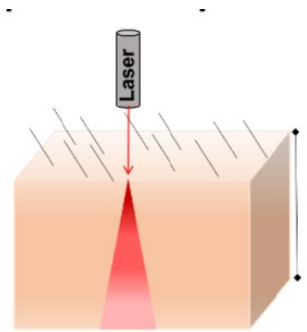


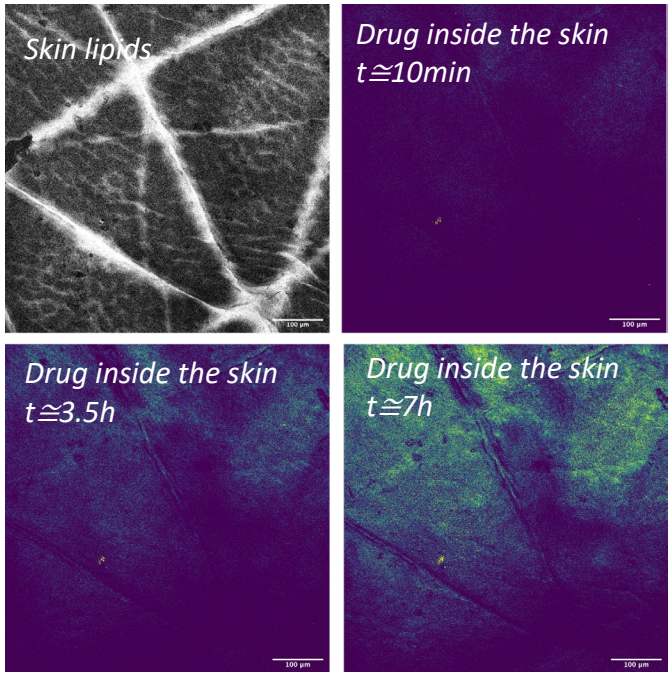


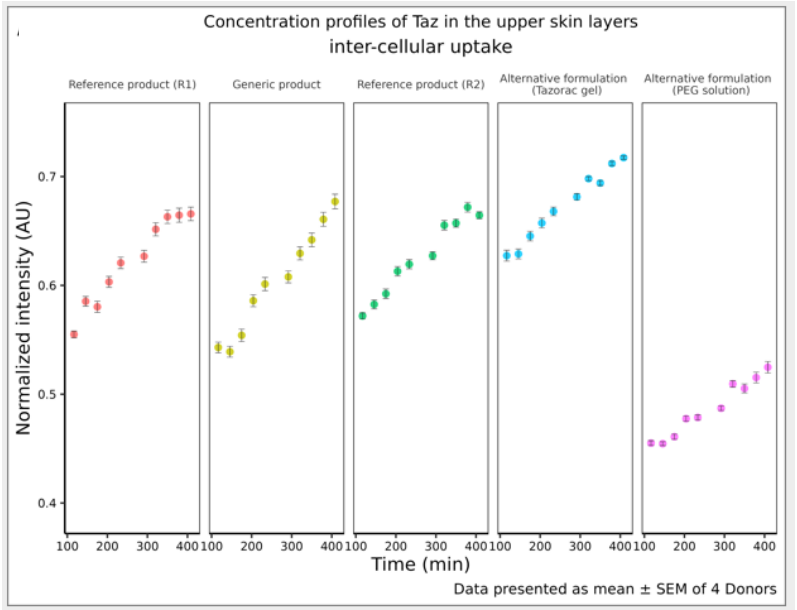
Dr. Richard Guy provided with FDA funding for award U01FD0006533

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.

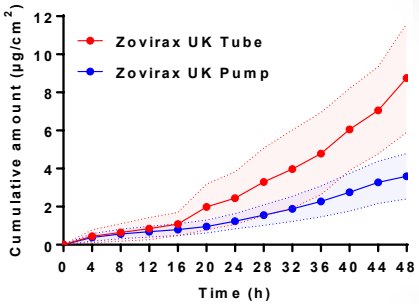






Dr. Conor Evans provided with FDA funding for award U01FD0006698

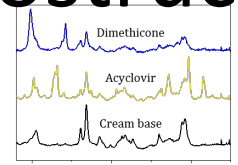
Understanding Product Microstructure

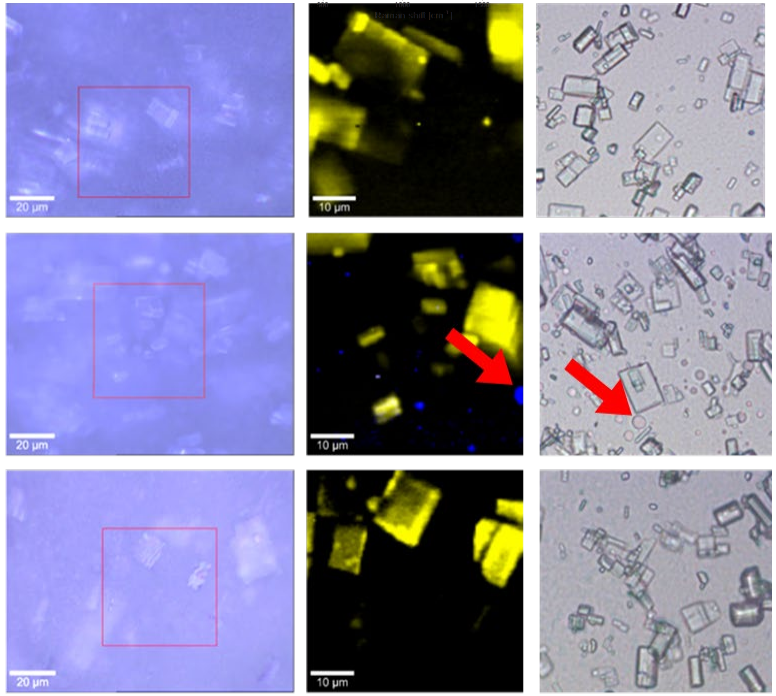


Zovirax® UK
Tube

Zovirax® UK
Pump

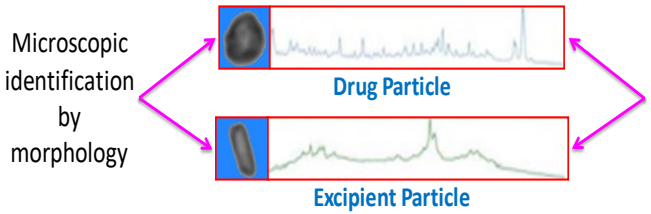
Zovirax® UK
Pump
(from inside container)

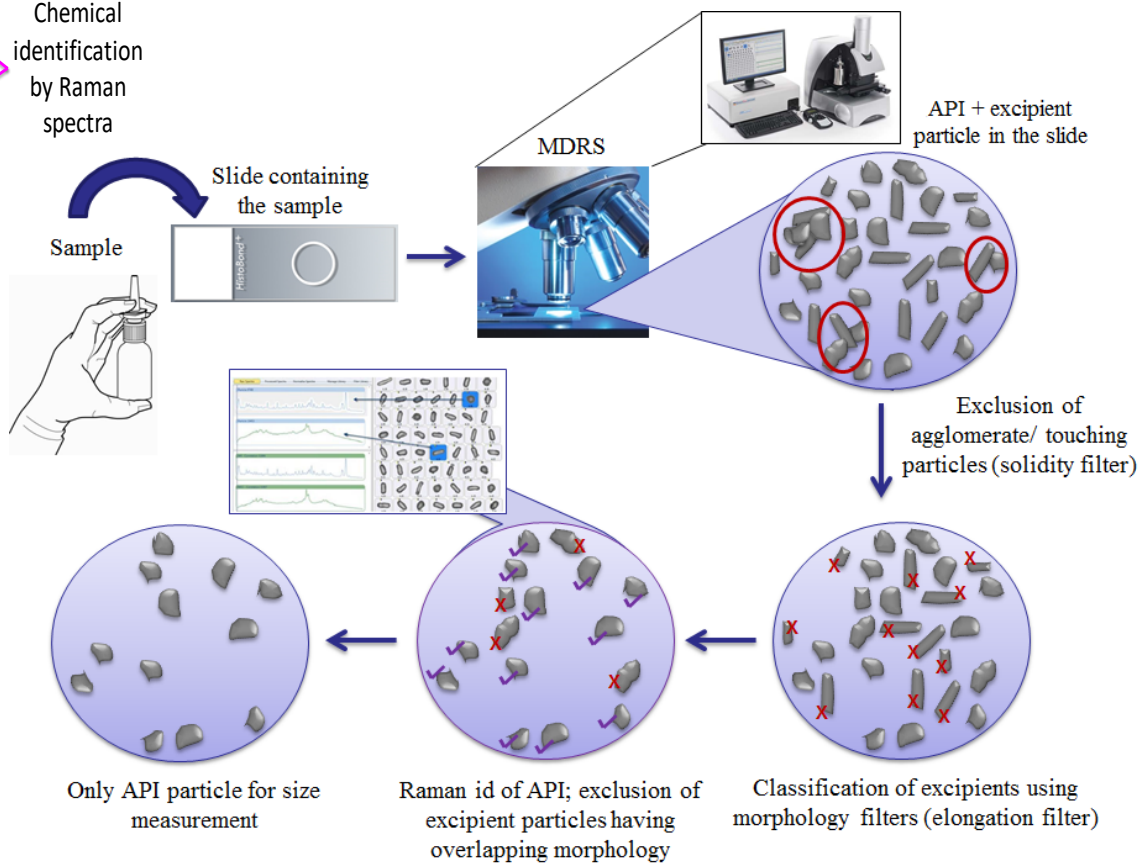




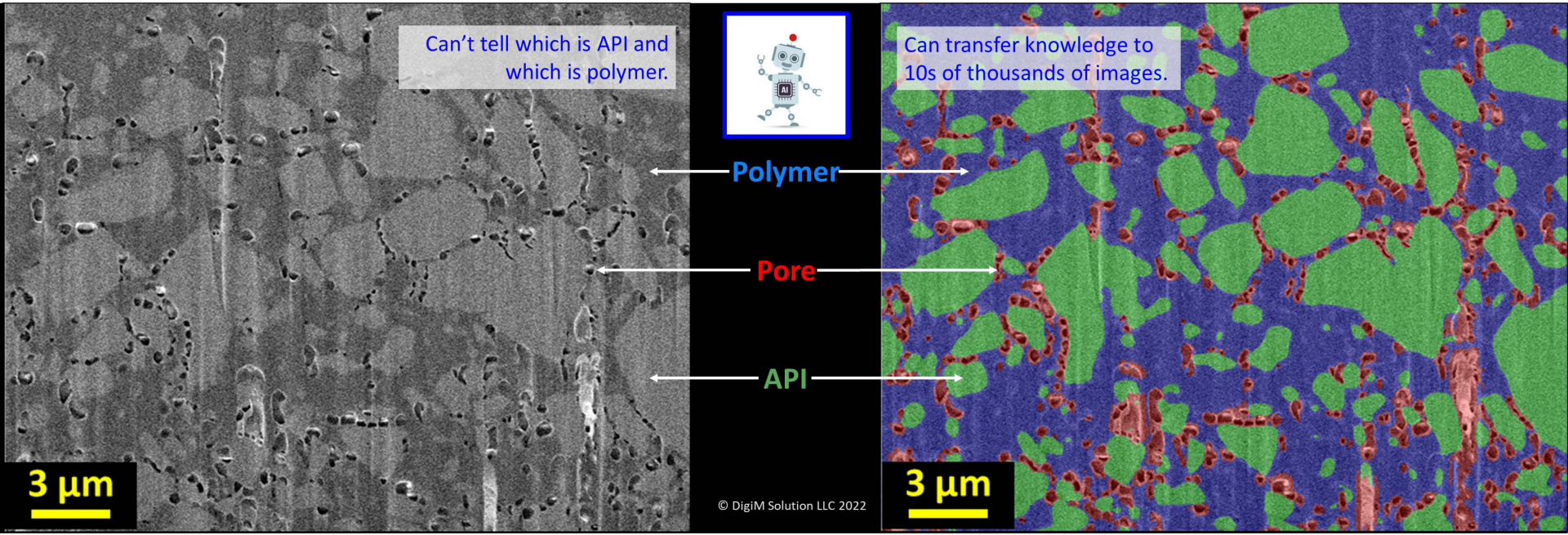
Prof. Michael Roberts provided with FDA funding for award U01-FD005226

Morphologically-Directed Raman Spectroscopy





Imaging and Artificial Intelligence



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

First-time Generic Drug Approvals 2022

Most Relevant to Dermatology (out of 90 total)

ANDA #	Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indication
212710	Penciclovir Cream 1%	Teva Pharma	Denavir	11/9/2022	Recurrent herpes labialis
215433	Tazarotene Gel 0.05%	Cosette Pharma	Tazorac	9/13/2022	Plaque psoriasis
208768	Posaconazole Injection	Par Sterile	Noxafil	5/25/2022	Prophylaxis of invasive Aspergillus and Candida
215398	Bexarotene Gel	Amneal Pharma	Targretin	4/27/2022	Cutaneous lesions of CTCL
214596 212424	Phytonadione Injectable Emulsion	Cipla	AquaMEP HYTON	4/22/2022	Coagulation disorders caused by Vitamin K deficiency

First-time Generic Drug Approvals 2023

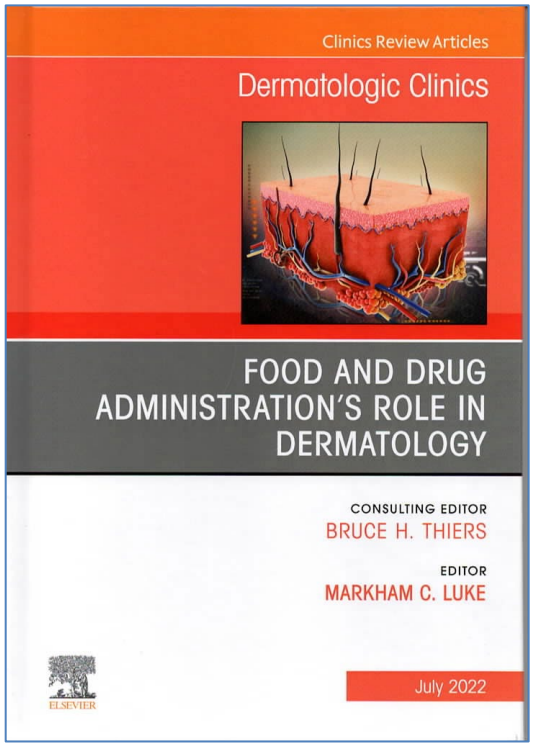
Most Relevant to Dermatology (out of 32 total)

ANDA #	Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indication
213267	Thalidomide Capsules	Natco Pharma	Thalomid	4/27/2023	Cutaneous manifestations of moderate to severe erythema nodosum leprosum
214688	Calcipotriene/ Betamethasone Foam 0.005%/0.064%	Glenmark Pharma	Enstilar	3/21/2023	Plaque psoriasis
209738	Tofacitinib Tablets	Microlabs Ltd	Xeljanz	3/13/2023	Rheumatoid and psoriatic arthritis
215408	Doxepin HCl Cream, 5%	Teva Pharma	Zonalon	2/17/2023	Moderate pruritis in adult patients with AD or LSC

10th Anniversary for Indoor Tanning Bed Reclassification

- FDA/CDRH regulates indoor tanning beds/booths.
- Regulated as Class 1 – low risk - devices until June 2014, when they were reclassified to Class 2 – higher risk.
- As part of the reclassification, indoor tanning beds have a boxed warning regarding safety and recommendations not to used by children.
- Notable reduction in the use of UV indoor tanning, in favor of spray tanning booths.

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

Acknowledgements

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- Lei Zhang, PhD
- Robert Lionberger, PhD

Research Collaborators

Collaborations within FDA

All of our intra- and extra-mural collaborators

U.S. FOOD & DRUG ADMINISTRATION

Thank You

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