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# FDA's Regulation of Drug Products Used by Dermatologists and Dermatologic Surgeons

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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

Center For Drug Evaluation  
and Research

Center For Devices  
and Radiological Health

Center For Biological Evaluation  
and Research

Center For Food Safety  
and Applied Nutrition

Center For Veterinary Medicine

Center For Tobacco Products

National Center For  
Toxicological Research

## 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

# Drug Approvals – Dermatology

# Dermatology Relevant FY2023 New Drugs



Drug Name	Active Ingredient	Approval Date	FDA-Approved Use
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
Zynzyz	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

# Dermatology Relevant FY2023 New Drugs



Drug Name	Active Ingredient	Approval Date	FDA-Approved Use
Filsuvez	Birch triterpenes	12/18/2023	To treat wounds associated with dystrophic and junctional epidermolysis bullosa
Ogsiveo	nirogacestat	11/27/2023	To treat adults with progressing desmoid tumors who require systemic treatment
Bimzelx	bimekizumab	10/17/2023	To treat moderate to severe plaque psoriasis in adults who are candidates for systemic or phototherapy
Xdemvy	lotilaner	7/25/2023	To treat Demodex blepharitis
Ycanth	cantharidin	7/24/2023	To treat molluscum contagiosum in adults and children 2 years and over

# 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 HYTOM	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
215609	Tretinoin Gel Microsphere 0.08%	Encube Ethicals	Retin-A Micro Gel	8/22/2023	For topical treatment of acne vulgaris
215266	Halobetasol Propionate Topical Foam	Padagis Pharma	Lexette Topical Foam	8/11/2023	Plaque psoriasis
213267	Thalidomide Capsules	Natco Pharma	Thalomid	4/27/2023	Cutaneous manifestations of 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

# Role of Drugs in Energy-based Surgical Procedures and Care of Patients



- Non-surgical intervention
  - GLP1-like agonists, botulinum toxin
- Anesthesia
  - Systemic, Regional, Local
- Anti-infectives – systemic, topical
- Treatment of pain post-operatively
  - NDAIDs, opioids



# Relevant FDA Milestones

# 40<sup>th</sup> Anniversary of Hatch-Waxman



- Also known as the Drug Price Competition and Patent Term Restoration Act this was effective from September 24, 1984
- The Act established the modern system of generic drug regulation in the United States
- The Act included provisions for patents and exclusivities for new drug and abbreviated new drug applications (NDAs and ANDAs)

# 20 years since Biologic Drugs Migration

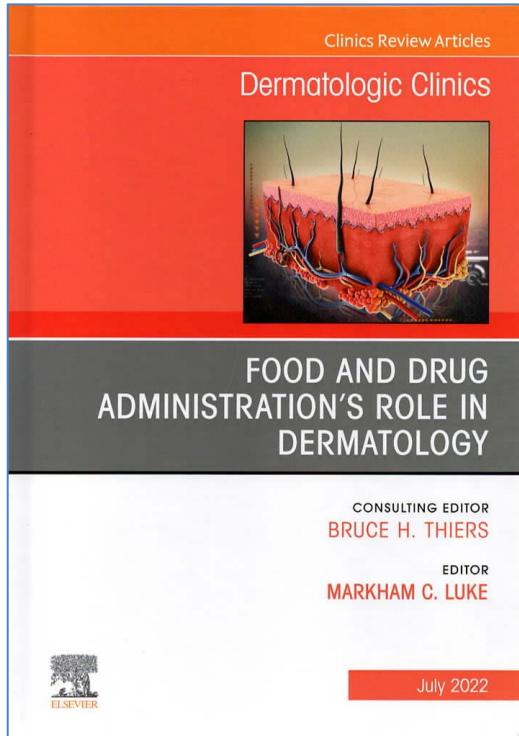


- In 2003-4, biologic drugs were migrated from CBER to CDER. This includes drugs like botulinum toxin.
- Since then, great strides have been made in the regulation of biologic drugs, including the advent of biosimilars.
- Biosimilars, under user fee provisions have advanced with regard to their own regulatory science and research program.

# Over 12 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)

# 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



# Thank You

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