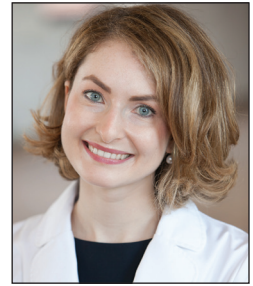


Over-the-counter Topical Products in Dermatology

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RESIDENT PEARLS

- Several branches of the US Food and Drug Administration are responsible for regulation of over-the-counter (OTC) topical products with both direct and indirect oversight.
- There are several excellent resources available to dermatologists in training who are interested in learning about pharmacology and tolerability of OTC products.
- Firsthand experience in personally sampling a variety of products also helps clinicians provide practical recommendations to patients.

Dermatologists must be familiar with the safety, utility, and tolerability of a range of over-the-counter (OTC) products. In this article, the role of the US Food and Drug Administration in regulating safety of OTC products is discussed. Additionally, resources to help guide clinicians to learn about the pharmacology and tolerability of OTC products are reviewed.

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Over-the-counter (OTC) topical products commonly are discussed during dermatology encounters. Unsurprisingly, dermatologists recommend OTC topical formulations at the highest rate of all medical specialists.^{1,2} These products may aid in the treatment of skin disease and include shampoo for seborrheic dermatitis, moisturizer for atopic dermatitis, and an armamentarium of products for acne. Conversely, an incorrect selection of OTC topicals can cause or exacerbate skin conditions or result in systemic toxicity. This article addresses how dermatology residents may become familiar with the safety, utility, and tolerability of these products.

Safety and Regulation

Over-the-counter products fall into one or more US Food and Drug Administration (FDA) categories, each of which is subject to a unique set of regulations. The FDA website (www.fda.gov/cosmetics and www.fda.gov/drugs) is an excellent resource for comprehensive and up-to-date information about categorization, safety, and regulation of these products.

Many OTC products are categorized as drugs, including topical steroids, antimicrobials, and sunscreens.³ Most of these products previously were available by prescription and became available OTC after sufficient postmarketing safety information.⁴ Once a drug becomes available OTC, monitoring relies on reporting from health care professionals.⁵ Notably, the safety of chemical sunscreens is being re-evaluated in light of recent data demonstrating serum levels in humans above the FDA limit for drugs exempt from further testing for carcinogenicity and reproductive and developmental effects.⁶⁻⁸

Cosmetics include moisturizers, cleansing shampoos, deodorants, makeup, perfume, and hair colors.⁹ For cosmetics, the FDA prohibits use of 11 categories of ingredients, encourages manufacturers to perform safety testing, and has the legal authority to inspect manufacturing facilities.^{9,10} The FDA does not require approval, testing, or disclosure of safety data prior to products going to market.⁹ Interestingly, soap represents a separate category with its own regulations, defined by its ingredients and its intended purpose.³

The FDA has the authority to regulate imported cosmetic products.¹¹ Unfortunately, imported cosmetic products have been reported to contain ingredients banned in the United States. For example, there recently have been several cases of mercury poisoning from bleaching creams imported from Mexico resulting in catastrophic neurologic

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damage.¹² Additionally, imported products sold OTC in the United States containing clobetasol were reported in the literature in 1994 and remain an ongoing issue.¹³

Another category relevant to dermatologists includes dietary supplements. The FDA is responsible for evaluating safety and labeling of products before marketing and taking action against any adulterated or misbranded dietary supplement.¹⁴ The FDA does not directly test products, though third-party agencies including NSF International and United States Pharmacopeia impart certification after verification that labeled ingredients are present in the product and test for contaminants.^{15,16}

Utility and Pharmacology

Dermatology residents may have less experience and comfort with the safety profiles and indications of nondrug ingredients in topical products. The textbook *Comprehensive Dermatologic Drug Therapy*¹⁷ is an excellent initial resource for learning about the mechanism of action, efficacy, pharmacology, and side effects of such ingredients, including hydroxy acids, shampoos, cleansers, sunscreens, insect repellents, and topical antioxidants. Dermatology residents also need to be familiar with ingredients causing allergic contact dermatitis, and *Fisher's Contact Dermatitis*¹⁸ is an excellent resource.

When patients indicate use of a particular product, clinicians may not be certain about specific ingredients. In this case, they may refer to the Walgreens website (www.walgreens.com), which provides an ingredient list for all products that they sell. Additionally, the Environmental Working Group's Skin Deep program (www.ewg.org/skindeep) maintains a database of more than 85,000 personal care products, which may be accessed online or using their mobile application (Healthy Living), which allows one to scan a product's barcode.

Trying Them Out

Lastly, it is helpful for dermatologists to be personally familiar with a variety of products to address patients' concerns regarding tolerability of products (eg, greasiness, inability to "rub in," sunscreens leaving a white cast, drying effect of cleansers). Samples at conferences including the annual meeting of the American Academy of Dermatology provide a cost-effective way for residents to try out a variety of products. Additionally, residents may purchase different products each time they restock their own supply of personal care products to sample a variety.

Final Thoughts

The FDA website contains up-to-date information on the safety of OTC products, which is constantly in flux. This article provides additional references for dermatology residents to begin to learn about the safety, utility, and pharmacology of topical OTC products. Firsthand

experience by sampling products helps dermatologists answer questions regarding tolerability.

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