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Men, Makeup And Drugs

Law360, New York (July 25, 2012, 1:06 PM ET) -- Men's grooming and beauty products, namely cosmetics for men, continue to experience yearly growth. The forecasts of one research firm predict that sales of men's toiletries will hit $3.2 billion by 2016, up from $2.2 billion in 2006. Sales of men's skin care products like facial cleansers, moisturizers and exfoliants grew more than fivefold from 1997 to 2009, to $217 million from $40.9 million.

Increasingly, men are dabbling in concealers, moisturizers, masks, serums and a host of other cosmetic products that were formerly considered to be exclusively for women. Retailers have experienced the most success with cosmetic products for men that have masculine but nondescript packaging.

So while the marketing of cosmetics and beauty products for men is gaining traction and holds promise for new entrants, the legal challenges in bringing a new cosmetic product to market are complex and merit legal attention.

The cosmetics industry in the U.S. is regulated by the Food & Drug Administration. Under the Federal Food, Drug and Cosmetic Act (FDCA) cosmetics are "articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness or altering the appearance."

This definition includes moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors and deodorants, as well as any substance intended for use as a component of a cosmetic product — but not soap, which is governed under different rules.

The FDCA also governs the manufacture and marketing of drugs. A cosmetic will also need to comply with the requirements for drugs if it is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."

Under this definition, a cosmetic that addresses a malady, such as dry skin, or affords protection, such as SPF in sunscreen, will also qualify as a drug. By illustration, dandruff shampoos, toothpastes with fluoride and deodorants with anti-perspirants are simultaneously cosmetics and drugs and therefore must comply with FDA guidelines pertaining to both.

Since the FDCA labels substances as cosmetics or drugs according to use, it is important to understand the principles that determine use. Claims about a product in its marketing materials may change the product's classification from a cosmetic to a drug.

For example, a product called “Line Away Temporary Wrinkle Smoother” was found to violate FDA regulations because its advertising claimed, “Line Away is not a facelift, not a treatment. It's a clear protein cosmetic. Contains absolutely no harmful chemicals, no hormones.” Line Away in fact was a solution of bovine albumen that formed a film when it dried on the skin. As the film dried, it tightened the skin as a mechanical side effect.

Despite its purely mechanical effect that had no lasting impact on the structure of human skin, the court found that the product’s reference to protein “strongly reinforces the impression that this is a therapeutic product, the protein content of which has a tonic or otherwise wholesome physiological effect upon the skin itself.”

While advertisers often engage in puffery, claims about a product that make it sound more traditionally therapeutic will transmogrify an otherwise wholly cosmetic product into a drug in the eyes of the FDA.

Assuming a cosmetic product avoids any complication from exhibiting drug-like uses or properties, it does not need to be approved by the FDA before it goes to market, with the exception of products containing certain color additives. Drugs, by contrast, must receive pre-market approval through the new drug application (NDA) process or conform to a “monograph” for a particular drug category, as established by FDA's over-the-counter (OTC) drug review. Receiving FDA approval for drugs is a complex process in its own right and is outside the scope of these materials.

A cosmetic product must not be introduced into interstate commerce if it is adulterated or misbranded in any way. “Interstate commerce” applies to all steps in a product's manufacture, packaging and distribution.

Adulteration can include: bearing a poisonous substance, consisting in whole or in part of any filthy, putrid or decomposed substance, or being packed or prepared in a way that it could become contaminated with filth.

Misbranding a product can include: false or misleading information or packaging, failure to follow labeling laws, or poor readability of required information.

Cosmetic products must comply with labeling regulations outlined in Title 21 of the Code of Federal Regulations, parts 70-740. Any false or misleading statements on the label or the failure to comply with the labeling regulations will expose the supplier to liability for false advertising and any number of FDA enforcement actions. The agency may: request a federal district court to issue a restraining order against the manufacturer or distributor, seize the goods in question or file criminal charges against a person violating the law.

Additionally, no cosmetic may be labeled or advertised with statements suggesting that the FDA has approved the product. The label must display the nature and use of the product, and a statement about the product’s quantity of contents. A cosmetic firm does not have to test the safety of any of its ingredients so long as it displays a warning on the product, disclosing its untested status.

That said, a supplier is ultimately responsible for the safety of its products and any ingredients used in its products. Additionally, there are some ingredients that are specifically off limits for cosmetic use, and the FDA maintains such guidelines.

Selling cosmetic products en masse to men will remain a challenging but steady growth opportunity for the industry. Companies looking to enter this market must use caution in the marketing, formulation and labeling of their products, lest their solely cosmetic product ends up in the regulatory thicket of the FDA rules governing drugs.

In addition, in order to keep operations unblemished, companies looking to cash in on the men's grooming renaissance should use care to avoid embellishments in their marketing claims.

This article originally appeared on Fashion & Apparel Law Blog.

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