Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Cosmetics Companies Using Instagram Face Regulatory Risk

By **Dominick DiSabatino** (March 7, 2018, 5:21 PM EST)

Dominick DiSabatino

As bitter cold and dry winds pummel most of the U.S. this winter season, consumer cosmetics companies are implementing marketing strategies and finalizing advertising campaigns that trumpet the benefits of skincare products such as anti-aging remedies, skin rejuvenation serums, blemish and dark spot correctors, plumping treatments and more. And for good measure — the stakes are high, as nearly $37 billion of the roughly $62 billion U.S. cosmetics market is driven to U.S. cosmetics companies for skincare products alone. To be sure, while a handful of very large brands occupy a majority of this $62 billion market, smaller organizations and startups are attempting to gain an edge by analyzing industry statistics and investing corporate resources into social media advertising, specifically Instagram. But in an industry that borders closely the highly regulated drug market, cosmetics companies of all sizes need to be wary of regulatory risk in their Instagram marketing strategies.

Instagram marketing has become a powerful revenue boosting tool. Indeed, active advertisers on Instagram doubled from one to two million between the second and fourth quarters of 2017. During that same timeframe in 2017, Instagram business profiles nearly tripled, from 8 million to 25 million. Instagram reports that about 80 percent of roughly 800 million monthly Instagram users will voluntarily connect to business advertising on the social media platform. And more than just connecting, Instagram users are further interacting with Instagram businesses or business accounts, perhaps around 180 million interactions per month, by requesting product information and providing feedback. Simply stated, the market is huge and trend exposure presents a remarkable opportunity to drive sales.

The Instagram format constitutes the ideal vehicle for product promotion by cosmetics companies. Instagram provides a clean, easily digested format to view image and text claims simultaneously. For example, the classic before-and-after photo array can be organized either within the same pane or as part of a multiple-photo post, complete with image customization, tagging, linking and text presentation. Users can also post and comment, providing personal experiences or results. Companies may also utilize celebrity brand ambassadors, including social media influencers, and sponsor tutorials. Another more recent iteration is the independent consultant model, not unlike the “Avon Lady” model, where everyday users promote the company’s products to their own social networks by using company-provided advertising material that users can post and customize. Instagram can really do it all.

Yet every cosmetic company knows — or should know — that keeping a watchful eye upon advertising

is the U.S. Food and Drug Administration, the regulatory agency tasked with, among other things, protecting public health by imposing very strict requirements upon what the FDA defines as "drugs." Today, many cosmetic products toe the line between lightly regulated "cosmetics" and highly regulated "drugs" to, among other reasons, underscore a product's market differentiation. The term "cosmeceutical," although formally unrecognized by FDA, highlights this industry effort to associate sophisticated technologies with cosmetic products in order to gain a marketing edge over competition. However, looming is this distinction between a "drug" and a "cosmetic" because crossing that line can cause a major headache with the FDA, including severe enforcement action.

So how does FDA evaluate these distinctions, and how might that affect social media marketing strategy? The Federal Food, Drug and Cosmetic Act (FD&C Act) and associated federal regulations bestow the FDA with broad regulatory oversight over a variety of consumer products, including drugs and cosmetics, but limiting the scope of this oversight are the underlying fundamental definitions. For example, the FD&C Act defines drugs, in relevant part, by their intended use — articles intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease and articles intended to affect the structure or any function of the body. Drugs must go through a lengthy, expensive review and approval process and are governed by very strict marketing rules, including specific limitations on social media. The FD&C Act also defines cosmetics, in relevant part, by their intended use — 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. Cosmetics require no approval from the FDA and can be marketed on social media with few restrictions.

Fortunately, the FDA provides plenty of comment regarding the distinction between drugs and cosmetics. At the outset, products with FDA-regulated active ingredients (i.e., certain alpha and beta hydroxyl acids and phthalates, etc.) may require, among other things, FDA-approved over the counter (OTC) labeling and compliance with FDA regulations regarding allowable claims for such OTC ingredients. Things get a bit trickier, however, when there are no such ingredients. The FDA will of course consider all information presented on product packaging, labeling and marketing and advertising materials — including those on social media platforms — with an eye to the above-mentioned FDA definition of a drug. That definition delineates two channel markers of product claims that should be avoided — product claims aimed at affecting the structure or function of the body or use in mitigation, treatment of prevention of disease. So, claims that a product might "stimulate collagen production," "promote cellular generation," "combat eczema" or "sooth dermatitis" are easy targets for FDA enforcement.

But even these helpful FDA distinctions between drugs and cosmetics do provide strong assurances because the FDA will also consider consumer perception of product claims. That is, why is the consumer buying this product, and what does the consumer expect the product to do? Herein lies the difficulty for seemingly innocuous cosmetic product claims to be deemed by FDA as drugs — the FDA makes clear that a product can be both a cosmetic and a drug based upon its intended use. What if a skin cleanser, containing non-OTC ingredients only, claims to reduce the appearance of acne blemishes? What if a moisturizer claims to enhance or boost collagen? Or how about a product that, if used, can allow the user to say goodbye to eczema, psoriasis or rosacea? Instagram marketing underscores these concerns because of the manner in which photos, captioning and commenting can all be considered by the FDA as impacting the consumer expectations for the product. What if the text claim doesn't specifically state a drug benefit, but when read together with a before/after photo or user experience comment, one could deduce that the overall message of the Instagram post was to cure a condition or affect skin function?

Depending upon the FDA's view (or a well-argued letter from a competitor to the FDA regarding the product), the result could be that post is an illegal "drug" ad, resulting in disciplinary action. This

enforcement action might be in the form of a warning letter — a public indictment and immediate demand that the company cease product marketing and conform to federal laws. The FDA issued a record number of warning letters in 2016 to cosmetics companies addressing topical skincare preparations that, according to the FDA, contained drug claims thereby rendering those products as marketed illegal for sale to consumers. This slew of warning letters far eclipsed the number of warning letters from the years 2007-2015. In May 2017, Sens. Diane Feinstein, D-Calif., and Susan Collins, R-Maine, reintroduced a 2015 bipartisan bill entitled Personal Care Products Safety Act, and separately, Sen. Orrin Hatch, R-Utah, introduced a bill entitled FDA Cosmetic Safety and Modernization Act.[2] These bills would, among other things, allow the FDA to test cosmetic ingredients and keep closer tabs on how companies make cosmetic products and deal with safety issues.

In 2017, however, the FDA dialed back enforcement activity, issuing only 10 warning letters to industry, and the Senate bills — like the many bills introduced in both the House and Senate over the years — have since languished. Moreover, the FDA withdrew FDA Import Alert, 66-38 "Skin Care Products Labeled as Anti-Aging Creams (IA 66-38), which cited claims that the FDA would view a product as "drug" (and thus denied entry into the U.S.) if associated claims state product will "counteract" or "retard" the aging process, or "rejuvenate," "repair" or "restructure the skin." The administration change in 2017 may have contributed to this bounce back in FDA enforcement, but now more than ever companies should reevaluate marketing campaigns — especially those leaning heavily upon social media — to ensure compliance with federal law governing cosmetics and drugs.

The key for cosmetics companies — especially those just getting off the ground and utilizing social media buzz — is to have an honest conversation about the product, its intended use and how it will be perceived in the marketplace amongst consumers. Consider product claims from the FDA's perspective (or that of an eager competitor) — is the claim aimed at treating a condition or changing the structure or function of skin? Does it call out a disease or condition, implying effect? If the answers in any way could be perceived as "yes," consider modifying the wording or rethinking the branding strategy to reduce regulatory risk. There are no simple answers, and of course, some claims carry far more risk than others, but the FDA's determination regarding the intended use of a cosmetic product can thus have drastic consequences for cosmetics companies, including but not limited to public reprimand, seizure of products, criminal prosecution and fines.

Dominick P. DiSabatino is an associate with Loeb & Loeb LLP in New York.

[1] S.1113, 115th Cong. §1 (2017)

[2] S.2003, 115th Cong. §1 (2017)