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Management Alert

An Update: Cosmetics and Personal Care Products Regulation and Litigation

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As 2019 is underway and the government is back up and running (at least for now), we have summarized for you key developments from 2018 and projections for 2019 on issues that we have been monitoring closely in the cosmetics and personal care products space. May these topics highlight where to fill compliance gaps and take risk-adverse measures to avoid litigation.

"C" is for…

Cannabidiol (CBD) competed with Vitamin C as a top ingredient in new cosmetic products this past year, with promises of having anti-inflammatory effects and other healing properties. Amid the hype, at the end of 2018, the Agriculture Improvement Act of 2018, P.L. 115-334 (the "2018 Farm Bill") was signed into law, changing the marketing of hemp and derivatives of cannabis and further removing hemp from the Controlled Substances Act thereby making it no longer an illegal substance under federal law. *See* Section 297A. The 2018 Farm Bill amended the definition of "hemp" to specifically include "all derivatives, extracts, cannabinoids," which has been construed as an attempt to include hemp-based CBD under the definition of industrial hemp. The 2018 Farm Bill allows, subject to certain restrictions, hemp cultivation, along with the sale, transport (including via interstate commerce), and possession of hemp-derived products.

Despite the major move in hemp legalization, the Food and Drug Administration ("FDA") still reigns over CBD. When the 2018 Farm Bill passed, the FDA issued a press release acknowledging the "growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD)." The FDA communicated its commitment to "advance new steps to better define public health obligations in this area" and "continue to closely scrutinize products that could pose risks to consumers." Critically, the press release warned that it is unlawful to introduce into interstate commerce food, including dietary supplements, containing CBD absent FDA approval, *regardless of whether the substance is hemp-derived* (because CBD is an active ingredient in FDA-approved drugs). The FDA further advised that there are pathways available to seek approval from the FDA to market such products, such as Epidiolex (the first drug containing CBD to be approved by the FDA for the treatment of epilepsy), and that the FDA is also considering its authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement.

Therein lies some confusion as to the effect of the passing of the 2018 Farm Bill and the FDA's interpretation of its authority—hemp and hemp-derived products have been officially removed from the Controlled Substances Act (*i.e.* no longer treated as a drug) but the FDA maintains that regardless of their source, CBD products, including those derived from hemp, and, at least those used in food and dietary supplements, are still subject to pre-market approval by the FDA. The 2018 Farm Bill was intended to aid farmers so that they can grow hemp for industrial applications and apply for grants and

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insurance to do so. Although related, legislators have not expressly authorized the extraction of CBD from hemp plants for human consumption as a food additive, dietary supplement, or medication. The FDA has determined though that hulled hemp seeds, hemp seed protein powder and hemp seed oil are safe for use without FDA approval and thus added to the Generally Recognized as Safe (GRAS) list. Hemp-derived CBD was not among the hemp derivatives added to GRAS and the FDA confirmed that these new GRAS conclusions "do not affect the FDA's position on the addition of CBD and THC to food", which is prohibited under section 301(II) of the Federal Food, Drug, and Cosmetic Act.

Notably, the FDA press release was devoid of any mention of CBD in cosmetic products or where included in a product *unintended* for medical use or oral consumption. The December 2018 press release is still informative in highlighting the FDA's attention to CBD and under the 2018 Farm Bill, the new regulatory scheme for industrial hemp. With new legislation and recent guidance from the FDA, we can expect even more clarity from the FDA on CBD products through further interpretation and application of the law via additional postings and enforcement measures, including warning letters. As stated in the press release, "[t]he FDA has sent warning letters in the past [the last of which were in 2017] to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer." CBD therefore still remains a controversial ingredient, but generally, we can expect greater production of hemp-based products.

Au naturel—but is it really?

In the wake of the "clean beauty" movement, existing retailers and new manufacturers alike have shifted their focus to chemical-free and synthetic-free products, removing ingredients like formaldehyde, artificial colors, phthalates and parabens. To communicate this transition to consumers, labels and marketing campaigns have ramped up their use of terms such as "natural," "organic," "green," "non-toxic," "wholesome," "botanical," "earth-friendly," "safe," "fresh" and of course, "clean." The use of such claims in advertising to consumers is not without risk.

The FDA, which regulates cosmetics, has not defined the term "natural" nor has it established a regulatory definition for this term in cosmetic labeling. With regard to food labeling, the FDA has issued informal, non-binding guidance that the term "natural" means that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food." Heeding to that definition, cosmetics advertised as "natural" should not contain synthetic or artificial substances that would not be expected to be in the product.

The FDA has also not defined the term "organic" for cosmetics. The U.S. Department of Agriculture (USDA), however, oversees the National Organic Program (NOP), which provides a definition of "organic" and further, provides certifications that agricultural ingredients have been produced under conditions that would meet the definition. The USDA has issued guidance for using the term "organic" for cosmetics and personal care products (although the publication is over ten years old). In short, if a product contains agricultural ingredients that meet the USDA/NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations and labeled accordingly. Pursuant to the USDA's regulations, to label a product "organic," it must contain at least 95% organically produced ingredients.

Use of the term "natural" has found a number of companies in hot water (H_20 is a chemical compound by the way—pun intended). Lawsuits, namely, class actions, have been brought under state and federal consumer protection and false advertising laws where the products have been advertised as "natural" but are alleged to contain synthetic ingredients. Products labeled "organic" have equally faced litigation for mislabeling where some ingredients have been linked to health concerns or otherwise do not meet the NOP's standards.

While there have been a number of lawsuits based on these terms, because they have been dismissed, stayed (pending formal definitions by the regulators), or settled, courts have been unable to offer more guidance on the issue. At least one court last year noted that "[d]etermining whether a reasonable consumer acting reasonably would find the term 'natural' deceptive when a product contains both natural and synthetic ingredients is a question this Court and Jury are well suited to entertain." *Petrosino v. Stearn's Prod., Inc.*, No. 16-CV-7735 (NSR), 2018 WL 1614349, at *10 (S.D.N.Y. Mar. 30, 2018). To date, neither the FDA nor FTC have brought an enforcement action against a cosmetics company premised on "natural" or

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"organic" but in 2019 or the near future, it may look to set a precedent for proper use of these terms and those connoting cleaner ingredients.

Social media, influencers, and the fine print

With social experiments highlighting the public's blind reliance on image and "influencers" coupled with exposure of fraudulent internet accounts, social media will likely fall under heightened scrutiny. Indeed, in the last year, the authenticity of influencers has been subject to criticism because of a number of so-called scandals revealing how much influencers are paid to either promote a product or critique a competitor. This realization has caused leaders in the personal care industry to call on influencer marketing to "clean up its act." While the concept of marketing through endorsements has been around for eons, such as athletes endorsing athletic wear, the use and reach of online bloggers through multiple platforms from Twitter, to Instagram, and other sites is subject to greater ambiguity (namely the relationship between the "reviewer" and developer of the product) and as a result, is susceptible to misleading consumers.

Clients using social media for marketing should afford such efforts with the same attention as other forms of media. Use of a celebrity or even a "minor" but growing blogger may require disclosures by the company, the endorser, or both to afford consumers with requisite transparency, especially about the relationship between the endorser and the product. In mid-2017, the FTC caught wave of the social media endorsements and issued 90 letters "reminding influencers and marketers that influencers should clearly and conspicuously disclose their relationships to brands when promoting or endorsing products through social media." In November 2018, the FTC settled a case involving a mosquito repellant company that relied on athletes to post online about the product's effectiveness without disclosing that they were paid to do so. These actions signal that companies need to be careful about properly disclosing endorser relationships so as to not mislead consumers into thinking the endorser is providing a neutral, unsolicited review.

The FTC has published helpful answers to FAQs and an Endorsement Guide to aid companies utilizing endorsements to promote a product. The FTC also recently provided pointers about what companies should do before planning a social media marketing campaign, including clearly disclosing paid promotional relationships. As companies begin to expand on their utilization of influencers and social media marketing, be it through longer partnerships or more controversial figures, companies should heed to the regulations governing endorsements.

Fake ~~news~~ consumer reviews

At the end of 2017, the Consumer Review Fairness Act (P.L. 114-258, 15 U.S.C. § 45b) took effect. As summarized by the FTC, the CRFA:

> makes provisions of form contracts between sellers and individual consumers void from inception if the provisions: (1) prohibit or restrict individuals from reviewing sellers' goods, services, or conduct; (2) impose penalties or fees on individuals for such reviews; or (3) require individuals to transfer intellectual property rights in such reviews. The Act also bars sellers from offering form contracts with such provisions. The Act contains certain exceptions, including for contract provisions that bar the submission of confidential, private, or unlawful information.

The FTC has set forth basic guidance for CRFA compliance. In August 2018 the FTC brought and soon settled its first case under the CRFA against a company for misrepresenting its earnings. In the course of selling programming and services to improve customers sales on an online market place, defendants in the case had customers sign "form contracts" that restricted customers from engaging in reviews, performance assessments, and similar analyses of the defendants' goods, services, and conduct. These contracts were entered in direct violation of the CRFA.

While the CRFA bars business activities intended to prevent people from giving honest reviews about products or services they receive, businesses should also refrain from activities that promote positive reviews where such reviews are not based on

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a consumer's truthful use. In 2018, at least one cosmetic company faced negative media coverage after a former employee leaked an internal, company email that insisted employees post positive reviews of a new product and even provided detailed instructions on what to say about the product as well as how to avoid tracing a review back to the company's IP address. To date, while the leak did not lead to legal action, it certainly resulted in immediate damage control.

The same concerns that apply to influencers apply to consumer reviews — ensuring transparency and honesty. Consumers should not be penalized for sharing their reviews and on the flip side, to the extent a reviewer is compensated in exchange for writing a positive review (*i.e.* paid, entered into a sweepstakes or receives free products), that relationship needs to be publically disclosed. In sum, the rule of thumb for customer reviews is that they should be truthful and honest and thus, short of selling products, retailers should steer clear of dictating the content. An exception to that standard applies when a consumer posts a review, of which a manufacturer is aware, that indicates an unintended use or result from a product. In response, the manufacturer should clarify the testimonial. For example, if a cosmetic company announces on Instagram a sale of its facial moisturizer intended for hydrating dry skin and a consumer posts about how that facial cream miraculously healed the customer's eczema, it may be incumbent upon the company to clarify to consumers on its Instagram page that the product is not intended to treat eczema, a medical condition. The FTC has provided guidance for these reviews, which are characterized as "testimonials that don't reflect the typical consumer experience."

The online universe *naturally* creates murky waters and should prompt cosmetic companies to take greater, pro-active online surveillance. The growing use of online media and easily manufactured consumer testimonials may present new opportunities for litigation or enforcement actions in 2019.

Indie Brands: their rise, their acquisitions, and the lawsuits they bring

From purportedly copying product names to copying product formulations, cosmetic competitors, including growing independent brands, filled the 2018 docket. A lawsuit that brought significant attention involved a multinational personal care conglomerate filing a patent infringement action against a young (approximately five years old) skincare company for selling an alleged copycat Vitamin-C serum at half the cost. To avoid being copied, many cosmetics companies avoid filing patents because it may require disclosing exact formulations of their products, but in this particular instance, the plaintiff did file a patent for its product. No results yet as the matter is still pending but the action may prompt companies to be more proactive in protecting their coveted intellectual property (the fountain of youth comes at a cost and after insurmountable research). However, in the growing push for "clean" cosmetics, query what variety will be left if the culturally-acceptable ingredient list continues to diminish.

In another case this past year, roles were reversed where a U.S. indie brand sued a celebrity-owned cosmetic company for trademark infringement for imitating its eyeshadow palette. Three weeks *after* the celebrity-owned company launched its "birthday special" product, the indie company filed a trademark for a product advertised under the same name that it had released ten months earlier. The complaint alleged that the product likely confused consumers to believe they are buying the genuine, original cosmetic from the indie company and that "inherently distinctive packaging, including the imprinting of quotations in the products," have also been copied.

With a plethora of cosmetic brands, it is hard for any brand to maintain a competitive edge, especially where larger, established companies have been known to quickly pursue acquisitions of successful indie brands. For example, between 2017 and 2018, Colgate-Palmolive acquired PCA Skin and EltaMD. While an acquisition may be the "finish line" for some aspiring start-up cosmetic companies, the foregoing lawsuits demonstrate the effect early IP safeguards, *i.e.*, trademarks, trade secrets, copyrights and patents, can have on potentially insulating a product and company from competition. On the other hand, these cases demonstrate that companies need to be aware of IP protections, so as to not find themselves in litigation for purported bootlegging.

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Class actions always lurking in the corner

Whether a newbie to the cosmetics industry or long-standing mogul, companies were exposed to 2018's fair share of class actions. In New York, a class action was filed against two popular drug-store cosmetic brands for allegedly misleadingly marketing products as "hypoallergenic" when, according to plaintiffs, they contain allergens, irritants, and other dangerous ingredients. Also in New York, another class action was filed against two different well-known drug-store brands for misleading packaging for liquid cosmetics based on the amount of liquid cosmetic advertised in the container without disclosing that consumers will not be able to access a large portion (sometimes more than half) of the product in the container because the pumps were allegedly defective. Also concerning representations of volume but as to the product's effect, a lawsuit was filed in California against a cosmetics company for allegedly misleadingly advertising that its mascara gives consumers 1,944% more volume when, according to the plaintiffs, the mascara did not work as advertised. Related to our discussion of "natural," separate class actions were brought in New York against a rising cosmetic brand and in California against a prevalent retailer for allegedly falsely marketing products as "natural" when they purportedly contain unnatural and synthetic ingredients.

This sampling of class actions from 2018 illustrates that consumers (or rather plaintiffs' counsel) not only continue to bring traditional false advertising claims based on product labels, *i.e.* stated ingredients and effects, but have also generated claims from the product itself and its packaging (*e.g.* slack fill). As a result, cosmetic manufacturers must not only ensure that product labeling and advertising is accurate but so too are the tangible features, including product content and size. Piggybacking on our earlier discussion of social media and online reviews, 2019 may see class actions premised on this activity, rather than the product alone. That is, consumer claims may stem from beyond the product and label to business activities surrounding online marketing of the product.

Push for regulatory reform

In light of all the foregoing developments, consumers and legislators alike have pushed for greater cosmetic reform. As we highlighted in April and October, 2018 saw a heightened interest in advancing legislation to regulate cosmetics by both the Senate and House, backed by support from industry leaders and famed celebrities. Amidst the mid-term elections, the call to action, that is, any true reform was projected to be delayed until this year or 2020. Eyes are on watch this year for the continued campaign for "clean" cosmetics and enhanced FDA oversight.

We continue to closely follow these issues and are well suited to assist you with compliance, private litigation, or government enforcement matters pertaining to cosmetics and personal care products. You can contact Tonya Esposito at *tesposito@seyfarth.com* and Renee Appel at *rappel@seyfarth.com*.

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