



The newest ingredients in cosmetics: CBD and probiotics

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INSIDER's take

- The determination of whether a product is a drug or cosmetic (or both) is based on the intended use of the product.
- Topical products with cannabis-derived ingredients that are not misbranded appear to be a low regulatory risk.
- FDA recently issued draft guidance for the use of probiotics in dietary supplements.

If you look around beauty aisles, chances are you'll be able to spot the two newest trends in cosmetics: products capitalizing on the CBD craze and cosmetics touting the benefits of their probiotics. Despite widespread popularity and excitement over these two trendy ingredients, their future in cosmetics is not entirely clear. On the one hand, the legality of CBD has not necessarily been established; on the other, the use of probiotics in cosmetics hasn't been sufficiently tested. In both cases, the claims being used to market these purported cosmetics raise questions whether these products should be treated as drugs or cosmetics.

Drug or cosmetic?

The Federal Food, Drug and Cosmetic Act (FD&C) defines drugs as products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body. Cosmetics, under the same law, are defined as products applied to the body to cleanse, beautify, promote attractiveness or otherwise alter the appearance.

Determining whether a product is a drug or cosmetic (or both) is based on the intended use of the product, which can be established from the claims on the product's labeling, advertising or other promotional materials, and/or from ingredients in the product that would cause it to be classified as a drug because such ingredients have a well-known therapeutic use.

The classification of a product as either a drug or cosmetic (or both) has implications for how such a product can be brought to market and how it is regulated once on the market. While FDA has oversight over both drugs and cosmetics, it only requires premarket testing and approval for drugs (whereas cosmetics are only subject to FDA oversight over their safety and efficacy after they're marketed to the public). FDA will review cosmetic labeling claims to ensure the claims are appropriate; if the product makes claims that are drug claims, FDA may deem the product misbranded. Additionally, FTC is responsible for reviewing advertising to determine whether it is unfair and/or deceptive and whether the advertising claims are supported by a "reasonable basis."

If a non-food product represents, either directly or by implication, that it will affect a structure or function of the body or diagnose, cure, mitigate, treat or prevent disease, then—in the U.S.—FDA would consider the product a drug. The question then, related to cosmetics seeking to capitalize on interest in CBD and probiotics, is whether these products are actually drugs, given some of the claims made; and if not, what is the added value of including CBD and probiotics in a cosmetic?

CBD

CBD appears to be everywhere lately—available as an additive in certain food and drink products, as an oil meant to be used as a dietary supplement, and as previously mentioned, as a cosmetics ingredient. While there is much excitement around CBD's purported ability to provide therapeutic benefits, there is uncertainty as to its legality, especially when it comes to its presence in cosmetics.

Under the Agriculture Improvement Act of 2018 (more commonly known as the “2018 Farm Bill”), industrial hemp-derived ingredients (including CBD) made from hemp grown under specific circumstances are no longer Schedule I (i.e., designated as having no therapeutic benefit with a high likelihood for abuse) under the Controlled Substances Act (CSA). The ability to manufacture, market and sell CBD products is still slightly complicated given the patchwork of state laws in effect. Further confusing the issue, following passage of the 2018 Farm Bill, FDA issued a press release acknowledging public interest in CBD, and the agency promised commitments to clarify public health responsibilities and evaluate new products that may pose risks to consumers.

FDA held a May 31 public hearing in response to industry requests for more definitive rules, but in large part, testimony focused on CBD's inclusion in food and dietary supplements. Further complicating CBD's future, the panel specifically questioned the added benefit of CBD, and its precise function, in cosmetics.

Currently, as long as a topical cosmetic product with cannabis or cannabis-derived ingredients doesn't make any false or misleading claims, does not make any disease-oriented claims or structure/function claims and is not adulterated (i.e., unsafe), there seems to be a low risk of attracting FDA scrutiny. Ultimately, given the abundant interest in CBD, products featuring the ingredient will likely face growing scrutiny from private litigants—and potential regulation by FDA and FTC depending on the types of product claims made.



Probiotics

Another cosmetic additive that engenders similar questions to CBD are probiotics. Probiotics—live microorganisms believed to provide health benefits when consumed—have been used for years in the food and dietary supplement markets, and it was not until recently that they've made the jump into cosmetics and beauty. When marketed in food, probiotics are promised to improve gut health and prevent digestive tract irritation, encourage the growth of “good” bacteria and promote a healthy immune

system. In skincare and cosmetics, manufacturers are promising probiotic products will soothe inflammation, strengthen the skin's natural barrier and maintain a healthy bacterial balance.

Despite the range of positive outcomes promised by marketers of probiotics, there is little to no consensus within the scientific community on the veracity of those claims. FDA does not currently regulate the use of probiotics in skin care and only recently issued draft guidance for the use of probiotics in dietary supplements. There is some concern that if probiotics alter the existing microbiome of the skin, the cosmetics that include probiotics could actually be considered a drug and thus subject to heightened FDA scrutiny and regulation. Given the use of preservatives in cosmetics, it's possible the microorganisms used would be considered postbiotics, or the metabolic byproducts from probiotics (and thus dead, not live, microorganisms).

While CBD and probiotics are seeing increased interest and market appeal, it is unclear what, if any, future these ingredients have in the skin care and cosmetics space. FDA has demonstrated an interest in providing guidance on the use of CBD and probiotics, which, until now, has been focused on food and dietary supplements. But it is increasingly apparent FDA officials will inevitably shift their focus to the cosmetics space as well. When they do, marketers and brands must be clear on what benefits CBD and probiotics add to skin care and cosmetics—or else face potential questions from FDA and FTC. 🌀



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