LITIGATION MINUTE: BEAUTY FROM WITHIN AND THE CONFUSING CLAIMS LANDSCAPE

BEAUTY AND WELLNESS SERIES: PART ONE OF THREE

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WHAT YOU NEED TO KNOW IN A MINUTE OR LESS

The current industry trend “beauty from within” refers to a focus on wellness—namely physical, mental, and lifestyle—and its impact on beauty. Oral supplements that consumers can use for aesthetic benefits to skin, hair, and nails are at the core of this trend.

From a US Food and Drug Administration (FDA) regulatory perspective, oral supplements fall under the food subcategory of dietary supplements. Beauty and cosmetic-type claims that are attractive under this trend—such as “helps reduce the appearance of fine lines and wrinkles”—can have unintended consequences. From the FDA's view, this claim applied to an oral supplement (rather than a topical cosmetic) transforms the oral supplement into an unapproved drug, as the claim—and others like it—purport to change the structure of the skin.

In a minute or less, here is what you need to know about marketing claims for beauty-from-within products.

The Triad: Cosmetic vs. Supplement vs. Drug Claims

A cosmetic or a dietary supplement can be viewed and regulated as a drug by the FDA simply based on the advertising claims made. Therefore, small overstatements or missteps could have big consequences.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), **cosmetics** generally refer to products applied to the human body for “cleansing, beautifying, promoting attractiveness, or altering the appearance," and permissible claims focus on these listed functions.

On the other hand, **dietary supplements** are products intended for ingestion and which contain substances (e.g., vitamins, minerals, herbs) to supplement the diet. Supplements are permitted to bear “structure-function” claims referring to a dietary ingredient and its ability to support or maintain an already-healthy structure (e.g., skin, eyes, or hair) or function (e.g., metabolism, digestion, or immune function) of the body.

Neither cosmetics nor supplements are permitted to bear **drug claims** that purport to “diagnose, cure, mitigate, treat, or prevent disease” or to “affect the structure or any function of the body” per Section 201(g)(1) of the FD&C Act.

Ironing Out the Wrinkles

The claims one can make on a “beauty-from-within” supplement versus a cosmetic can become confusing, particularly when the manufacturer markets both products for the same purpose. Certain types of claims

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consistently find themselves in the crosshairs of the FTC or FDA. The following generic examples highlight common arguments raised about the claim language alone, based on an amalgam of recent FTC and FDA actions.

Hypothetical Concept 1: Helps reduce the appearance of skin conditions (e.g. wrinkles and fine lines, redness).

- Acceptable Claim for Cosmetic: This claim for a cosmetic, such as a moisturizer, is typically acceptable, as it focuses on the product's impact on the appearance of the skin.
- Unapproved Drug Claim for Beauty-From-Within Supplement: As applied to an oral supplement, this claim could pose risks. It does not stay within the acceptable “maintenance” zone of a structure-function claim (e.g., “helps maintain healthy skin”), but rather purports to change the structure of the skin, an interpretation that would render this a drug claim.

Hypothetical Concept 2: Helps maintain (e.g. healthy skin and circulation).

- Unapproved Drug Claim for Cosmetic: Similar claims are often subject to arguments that the statement does not focus on cleansing, beautifying, promoting attractiveness, or altering appearance, and therefore does not fall within the realm of a cosmetics claim. Instead, arguments contend, the suggestion of a product impact on the structure of the skin classifies this as a structure-function claim, which is not permitted for cosmetics and which could render the product an unapproved drug.
- Acceptable Structure-Function Claim for Beauty-From-Within Supplement: This claim is unlikely to raise similar drug claim contentions for supplement use, provided there is proper substantiation.
- Substantiation Considerations: Regardless of a supplement's classification by the FDA as a drug or a dietary supplement, its advertising claims must be truthful, not misleading, and supported. Claims about the health benefits of supplements require substantiation in the form of competent and reliable scientific evidence of testing of the actual product. Generally, claims of health-related benefits for humans require randomized, controlled human clinical testing conducted in a methodologically sound manner and resulting in statistical significance (95% confidence level). The FTC and FDA have made public statements of an intention to harmonize their substantiation standards.

Hypothetical Concept 3: Increasing or Aiding in production of collagen.

- Drug Claim for Both Cosmetic and Beauty-From-Within Supplement: Topical cosmetic and oral supplement claims to increase or aid in the production of collagen or fatty issue have been interpreted as drug claims under the argument that such claims refer to a change in or impact on the structure of the skin. Aside from claim language itself, other factors, such as whether the active ingredient in the product has been approved by the FDA for a drug function, can impact this analysis.

Risk of Government and Class Action Enforcement

FDA regulatory distinctions regarding permissible claims for cosmetics versus supplements versus drugs are quite clear. It is also clear that one can locate many examples in the marketplace of cosmetics making drug claims in the form of structure-function claims and beauty-from-within supplements making drug claims in the form

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of cosmetic claims. However, this risk has not materialized into a spate of class action litigation like the current food arena.

Throughout 2017 and 2018, several manufacturers of biotin supplements marketed for healthy “hair, skin, and nails” (i.e., acceptable structure-function claims) were challenged in class action litigation for fraud, alleging that the products did not improve hair, skin, and nails. In other words, the claims alleged that there was not adequate substantiation to support the structure-function claims. These suits were largely unsuccessful.

Both the FDA and FTC have challenged cosmetic companies for claims and issued warning letters (e.g., pointing out drug claims being made on both cosmetic and supplement products). However, these are relatively few and far between given the number of products on the market.

Peering Into the Crystal Ball

The cosmetic and dietary supplement industries have enjoyed far less class action risk in the past 20 years when compared to the food industry. However, recent activity in California indicates that the same plaintiffs' attorneys who have cut their teeth on food may turn to the cosmetic and dietary supplement markets for new hunting grounds. This trend has already been observed in the Proposition 65 enforcement arena in California, where enforcement against cosmetics and supplements is increasing. Cosmetic and related companies capitalizing on this beauty-from-within trend may continue to take comfort from staying within a crowded pack in terms of claims, but they should also be aware of the risk. K&L Gates' Litigation and Dispute Resolution and Policy and Regulatory teams regularly counsel clients on the unique risks around FDA-regulated products.

As always, the beauty industry is bustling with new trends: some triggering noteworthy application of existing laws, as discussed in this piece, and other trends driving or working in parallel with new laws and precedent. In subsequent editions of this Litigation Minute series, we will focus on the tightrope walk entertained by cosmetic brands considering natural, clean, or ESG-based product claims, as evidenced by recent class action complaints. We will also explore the impact of emerging lifecycle and end-of-life product packaging laws and guidelines within the cosmetics industry, focusing on new state legislation and expanded brand responsibilities.

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