'Beauty From Within' Trend Poses Regulatory Risks For Cos.

By **Natalie Rainer and Katherine Staba** (April 26, 2024)

Natalie Rainer

Katherine Staba

The current beauty industry trend known as "beauty from within" refers to a focus on wellness — 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 U.S. Food and Drug Administration regulatory perspective, oral supplements fall under the food subcategory of dietary supplements. Beauty and cosmetic 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, a claim like this applied to an oral supplement, rather than a topical cosmetic, transforms the oral supplement into an unapproved drug, since the claim purports to change the structure of the skin.

On July 1, the FDA will begin enforcement of requirements under the Modernization of Cosmetics Regulation Act, passed in 2022. MoCRA imposes both facility registration and cosmetic product listing requirements on manufacturers of cosmetics sold in the U.S.

In addition, individual states continue to pass laws affecting FDA-regulated products. For example, New York's S.5823C/A.5610D bans the sale of muscle-building and weight-loss supplements to minors under age 18, and took effect on April 1.

These new legal measures may portend additional scrutiny of cosmetics and supplements by regulators — as well as spark the interest of class action plaintiffs.

Below, we review some important points about marketing claims for beauty from within products.

The Triad: Cosmetic, Supplement and 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, 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 that 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 consistently find themselves in the crosshairs of the Federal Trade Commission or the 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

The product is claimed to help reduce the appearance of a skin condition — e.g. wrinkles and fine lines, or redness. 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.

But 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

The product is claimed to help maintain healthy skin and circulation. This would be an unapproved drug claim for a 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, the suggestion of an 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.

This would be an acceptable structure-function claim for a beauty from within supplement. This claim is unlikely to raise similar drug claim contentions for supplement use, provided there is proper substantiation.

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 — a 95% confidence level. The FTC and FDA have made public statements of an intention to harmonize their substantiation standards.

Hypothetical Concept 3

The product is claimed to increase or aid in the production of collagen. This would likely be considered a drug claim for both a cosmetic and a 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 affect 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 of cosmetic claims.

However, this risk has not materialized into a spate of class action litigation, as in 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. The claimants alleged that the products did not in fact 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.

Natalie Rainer and Katherine Staba are partners at K&L Gates LLP.