happi

Status & Interventions Of the Skin Microbiome

Law & Order:
Addressing legal and production issues related to microbiome products

The Scalp Microbiome

What's Trending in Skin Care, Hair Care & Cosmetics

Table of Contents

happi
Household and Personal Products Industry

Legal Considerations for Marketing Skin Microbiome Products

Microscopic organisms on the skin could hold the next secret to good skin health—but with them come evolving regulatory and legal considerations for the personal care product industry.

Raqiyyah Pippins • *Arnold & Porter*

Consumer interest in the skin microbiome—the variety of bacteria, fungi and microorganisms that live on the skin—has burgeoned, as research develops suggesting that an imbalance in the skin microbiome is associated with various skin conditions such as atopic dermatitis and rosacea. Although the connection between these skin conditions and the skin microbiome is not yet conclusive, the personal care products industry has quickly begun to develop products aimed at improving or maintaining a healthy skin microbiome. Companies are now promoting products containing ingredients such as ammonia oxidizing bacteria, prebiotics, probiotics and postbiotics intended to protect the skin microbiome, including claims such as that the products "keep the skin's ecosystem in check," "respect the skin's pH and its microbiome," and "target concerns that may result from unbalanced surface skin bacteria."

The opportunity to develop new products also comes with

risk. While microbiome claims seem to have avoided scrutiny from competitors and regulators to date, they are not expected to fly under the radar for long. This article highlights three major risk areas that any company involved in the manufacture, sale, or marketing of personal care products with microbiome-related claims should be aware of as they contemplate capitalizing on increased consumer interest in the category.

Formulators must be careful not to make drug claims on their labels or in their advertisements.

Unintended Drug Claims

The first major watch-out for companies developing claims for skin microbiome-related products is whether the claims heighten the risk that FDA may regulate the product as a drug.

As background, a personal care product can be considered a cosmetic, a drug, or both under the Food, Drug, and Cosmetic Act (FDCA), depending on the intended use of the product. Products intended only for "cleansing" or "altering the appearance" are considered cosmetics under the FDCA, while products intended to treat or prevent disease, or to "affect the structure or function of the body" are considered drugs. Products intended both to cleanse or beautify and to "affect the structure or function of the body" can be considered combination drug-cosmetic products.

In the past five years alone, FDA has issued more than 50 warning letters to manufacturers of personal care products alleging the companies are making what the Agency views as unapproved drug claims in relation to these products. For example, FDA has taken the position that claims such as "stimulate skin renewal," "speed up the repair to DNA" and "defend against environmental triggers that cause [skin] pigmentation" are drug claims under the FDCA. Claims that a skin care product can "reduce bacteria, which greatly improves the skin's immunity against infection" and "inhibit the enzymes responsible for cartilage destruction" have also been viewed by FDA as drug claims. Against this backdrop, claims that a product can improve or otherwise affect the skin's microbiome present risk of regulation are drug claims by FDA as well—and thus should only be made with that risk in mind.

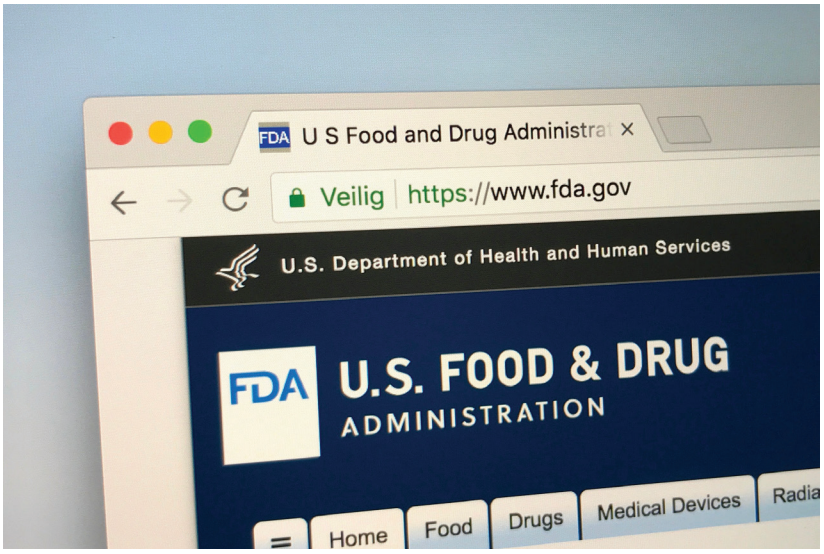
False Advertising

The marketing and sale of personal care products with microbiome claims may also trigger allegations of unfair and deceptive advertising practices under state and federal law.

Only FDA can enforce the federal Food, Drug, and Cosmetic Act. Some states, such as California, however, have unfair and deceptive advertising practices (UDAP) statutes that functionally enable private citizens to enforce the state Food, Drug and Cosmetic Act. In essence, under these statutes, a violation of the state Food, Drug and Cosmetic Act constitutes an unfair or deceptive advertising practice. In states where the state Food, Drug and Cosmetic Act mirrors the federal statute, plaintiffs' attorneys have filed suit against personal care product companies, alleging that use of a claim cited in an FDA warning letter causes the personal care product to be a drug and the company's marketing to be an unfair and deceptive advertising practice under state law.

For example, in Dasilva v. Infinite Product Company, the plaintiff alleged that Infinite Product Company violated California's UDAP statute by marketing topical CBD skin care products with unapproved drug claims such as, "[f]reeze away all aches and pains…painkiller and muscle relaxant" cited in a recent FDA Warning Letter. Similarly, in Reid v. GMC Skin Care USA Inc., the plaintiffs alleged GMC Skin Care USA, Inc., violated California's UDAP statue by promoting its "Phyto Stem Cell+" skin care line of anti-aging products with "unapproved drug claims" such as, "[i]mproves skin elasticity" and "[s]timulates collagen synthesis to reduce the appearance of fine lines and wrinkles." Should FDA issue a warning letter or other public statement alleging that certain claims regarding the skin microbiome constitute "drug" claims, companies should be on the watch-out for civil demands alleging that such FDA enforcement is evidence that the company's microbiome claims violate state law.

In addition, establishment claims regarding the efficacy of the products; i.e., clinically proven or improves the skin microbiome by X%, could draw the attention of the Federal Trade Commission. For example, in 2014, L'Oréal entered into a consent agreement with the Federal Trade Commission regarding claims that the company's Lancôme Génifique and L'Oréal Paris Youth Code skin care products were "clinically proven" to "boost genes' activity and stimulate the production of youth proteins



In the past five years, the US Food and Drug Administration has issued more than 50 Warning Letters to personal care product manufacturers.

that would cause "visibly younger skin in just 7 days," and would provide results to specific percentages of users.

In pertinent part, the FTC determined that the claims were deceptive because L'Oréal did not possess sufficient substantiation for the claims; i.e., "competent and reliable scientific evidence." Against this backdrop, a company may want to avoid "clinically proven" and quantified claims for its products absent robust testing supporting the efficacy of the product.

Product Safety

Cosmetic safety is receiving increased scrutiny by FDA, Congress and the public. In fact, in December 2019, the House Committee on Energy and Commerce Subcommittee on Health held a hearing on "Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety." FDA has also more publicly scrutinized safety issues of products, including topical products containing probiotics, noting, for example, its concern that the use of products containing live microorganisms could lead to infection. With this in mind, care should be taken during development of products intended to impact the skin microbiome to ensure the safety of the product. In addition, a robust consumer complaint system is advisable to closely monitor reports of adverse events experienced by consumers.

Increasing consumer interest in the skin microbiome creates opportunity for product development. Monitoring these key watch-outs can help companies to expand their product portfolio without expanding legal and regulatory risks beyond the desired risk threshold for the company. •

ABOUT THE AUTHOR

• **Raqiyyah Pippins is a partner at Arnold & Porter where she** focuses her practice in the areas of FDA's regulation of personal care products, food, dietary supplement, cosmetic, drug and medical-device products sold directly to consumers as well as FTC and state regulation of the marketing and sale of consumer products. Pippins represents companies that are engaged in the development, marketing, import and export of consumer products, including conventional personal care products, food, dietary supplements, drugs, cosmetics, medical devices, apparel and appliances. She also represents personal care and other consumer product companies in advertising challenges, including numerous challenges before the National Advertising Division (NAD) of the Advertising Self-Regulatory Council, and defends companies in investigations conducted by the FDA, FTC and state agencies regarding product marketing practices. She has been recognized by Chambers and Best Lawyers for effective counseling regarding advertising and FDA law, respectively.

Arnold & Porter has deep and time-tested experience representing personal care and other consumer product companies before the Food and Drug Administration (FDA), Federal Trade Commission (FTC), US Consumer Product Safety Commission (CPSC), Environmental Protection (Agency), and state agencies. Arnold & Porter counsels clients regarding product development and marketing strategies while managing regulatory, competitor challenge, and consumer class action risk. The firm works with companies to obtain the desired regulatory classification for their products, while also developing compliance policies and assisting in inspections, agency interactions and enforcement matters. Arnold & Porter's experience with every aspect of FDA, FTC, CPSC, EPA, and state and local enforcement, including both administrative and court proceedings, provides it with particular experience in handling regulatory issues that are the subject of simultaneous investigations and proceedings. The firm has extensive expertise defending companies.

More info: www.arnoldporter.com