AVOID AN FDA WARNING LETTER

FDA has issued at least 21 warning letters to cosmetics companies over the past 13 months (July 2015-August 2016), with the vast majority targeting claims violations. The following guide can serve as a tool for your brand as you develop marketing and labeling claims that convey product benefits and drive consumer interest without running afoul of regulations and provoking FDA.

IS YOUR OFFERING A SKIN-CARE PRODUCT?

NO
Your chances of being served with an FDA warning letter are markedly reduced. FDA's monitoring of online cosmetic claims is largely focused on the skin-care category where the most aggressive claims tend to appear.

YES
Take care with your claims. Eighteen of 21 FDA warning letters issued to cosmetics companies from July 2015 through August 2016 have cited skin-care claims on companies' websites that exceed the cosmetic definition enshrined in the Federal Food, Drug and Cosmetic Act (FDCA).

Questions to consider

Is your product for anti-aging skin care?

YES
You face a marketing challenge with inherent risks, as any claims suggesting that a product can affect body structure or function – e.g., the skin or underlying features/processes – are drug claims under the FDCA.

NO
It may not jump out at FDA from the universe of cosmetics marketed online, but you still should be cautious about claiming effects beyond moisturization, cleansing and aesthetic benefits.

Is it a **Serum** and/or **Eye Formula?**

Serums are some of the most potent cosmetic formulations on the market due to their high active-ingredient content, and associated claims are among the boldest that consumers encounter. **Eye products** designed to address some of the earliest signs of aging can be similarly loaded with active ingredients and just as competitively marketed. FDA's expectations for claims on these types of cosmetic products remain the same, however. If they impact body structure/function, they're unapproved drugs.

WARNING
Claims for Sevani Botanica's Eye Repair Age Defying Eye Crème and Advanced Omega Night Repair Serum, as well as Annmarie Gianni Skin Care's Anti-Aging Eye Cream and Anti-Aging Serum, were highlighted in recent FDA warning letters as violating the FDCA.

Is the word **"wrinkle"** in your product name?

These types of products may draw FDA attention. While the agency accepts that moisturizing skin – a permitted claim for cosmetic products – can make fine lines and wrinkles less noticeable, treating or removing wrinkles is heavier-duty business that, from FDA's perspective, exceeds the scope of what cosmetic products may do.

WARNING
Peter Thomas Roth Labs' Un-Wrinkle Turbo Line Smoothing Toning Lotion and TPR Holdings' Freeze 24-7 Instant Targeted Wrinkle Treatment are among wrinkle products named in recent FDA warnings for overreaching cosmetic claims.

Does your product name reference **"stem cell"** or **"DNA"?**

Such references can raise flags at FDA that a product is intended to do more than simply cleanse, beautify or alter the appearance of skin, potentially interacting with the user's body at a deeper level, rendering it a drug by FDCA standards. Claims about boosting gene activity also are potential liabilities.

WARNING
Hollywood Skincare and Crescent Health Center were hit with FDA warning letters in 2016 for claims on their DermaSet Stem Cell 3D Renewal Cream and Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream, respectively.

Is your product a **Brightening/Lightening/ Whitening formula?**

FDA considers skin lightening a drug effect and currently only allows use of hydroquinone as a skin-bleaching ingredient in OTC drug/cosmetic combinations. You may be better off claiming that your product can even skin tone, address discoloration or target dark spots than positioning your product as a hyperpigmentation treatment, but all such claims can be dicey. When in doubt, using "appearance" language may be the safest route – e.g., "reduces the appearance of dark spots."

WARNING
L'Oreal, Golden Caviar Skin Care and Skin Authority were all warned in 2015 for claims about dark-spot and/or hyperpigmentation treatment.

Is your product billed as a **"cosmeceutical"**?

FDA does not recognize the term "cosmeceutical" as a distinct category of products, but the agency has a keen understanding of how the term is deployed in the marketplace to suggest a cosmetic boasting pharmaceutical-like effects. This virtually screams "unapproved drug." Use of the term won't earn you a warning letter on its own, but it could prompt FDA to take a close look at your product claims.

WARNING
Sircuit Cosmeceuticals and Lavian Ltd., which markets *Dermelect* Cosmeceuticals, both received warnings in 2016 for unapproved drug claims on cosmetic offerings.

Are you making **collagen** claims?

BEWARE. Stating or implying that a cosmetic skin-care product can stimulate, promote or otherwise affect collagen production is among the surest ways to invite a scolding from FDA. And it's difficult to couch collagen claims in appearance language – "improves the appearance of increased collagen synthesis"? – so the safest move is to avoid collagen references altogether. Same goes for elastin claims.

WARNING
Eleven of 18 warning letters issued by FDA in the past 13 months to cosmetics firms for excessive skin-care claims – and more than half of all FDA warning letters to cosmetics companies for any reason during the period – have singled out collagen claims.

Does your product promote **skin repair** or **cellular regeneration**?

According to FDA, it shouldn't, not if it's a cosmetic. Those are structure/function benefits that identify purported cosmetics as unapproved drugs.

Other claims to avoid:

- Anti-inflammatory
- Sun- or UV-protective
  (if your formulation does not conform to conditions, including active ingredient usage, set forth in FDA's related OTC sunscreen drug monograph)
- Claims related to medical conditions including rosacea, eczema, dermatitis, acne or psoriasis
  (unless your combination cosmetic-drug product is formulated according to conditions specified by a relevant OTC drug monograph)

And keep in mind...

Whatever claims you attach to products, all cosmetics must be safe and properly labeled according to federal law. In the postmarket setting, adverse-event reports and/or voluntary recalls can lead to FDA probes and inspections, which subject companies to further enforcement risks.

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