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Avoid An FDA Warning Letter: A Compliance Tool For Cosmetic Claims

by

INFOGRAPHIC: The Rose Sheet's compliance guide highlights the most challenging cosmetic products to market competitively without running afoul of FDA regulations and the riskiest types of claims a company can use at a time of intensive agency scrutiny.

The marketplace may be changing, but FDA's stance on disease-treatment and body structure/function claims on cosmetic products is unwavering, with at least 18 warning letters issued to skin-care companies for claims violations over the past 13 months.

The below guide highlights claims, product types and even product names that can pose risks, potentially drawing unwanted FDA attention at a time of unprecedented enforcement activity.

A downloadable PDF version of the guide is available [here](#) with links to in-depth Rose Sheet coverage of recent warning letters and related enforcement trend analysis.

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?

<http://hbw.citeline.com/RS/08300>

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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 consum-

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Claims for Sevani Botanica's Eye Repair Age Defying Eye Crème and