



## A Rose by Any Other Name: Drug Claims Make Your Cosmetic a Drug

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Last month, FDA district offices issued Warning Letters to two cosmetic companies for making claims that established their products as drugs.<sup>1</sup> In finding that the products were new drugs requiring premarket approval, FDA highlighted both disease claims and claims about the therapeutic effect of certain ingredients.

### Background

Under the Federal Food, Drug, and Cosmetic Act, cosmetics are defined as articles intended for cleansing, beautifying, promoting attractiveness, or altering the appearance.<sup>2</sup> FDA's regulatory authority over cosmetics is minimal. Unlike drugs, cosmetics, with the exception of color additives, do not have to be pre-approved by FDA. Manufacturers are responsible for ensuring their own products are safe and properly made. Any claim for the treatment of disease, or claim that the product can affect the structure or function of the body would fall under the definition of drug.<sup>3</sup> While this might seem like a straightforward determination for products like traditional lipstick or nail polish, the line often gets blurry with skincare products. Some claims that a product can alter appearance, which is a permissible cosmetic claim, also suggest the product can treat a disease or alter the structure or function of the body, which are drug claims.

The claims FDA took issue with for these products include:

- Pure and potent botanicals deliver dramatic healing benefits that are powerful enough to combat eczema
- Use this treatment at the first sign of a blemish, as it is very effective at every stage — even on blemishes that have not fully surfaced
- Stimulates new skin cell production; increases collagen and elastin production
- Decreases hyperpigmentation from age spots and acne
- Powerful anti-inflammatory and anti-bacterial agents combat redness
- Research has shown that squalane is beneficial for clearing up difficult skin problems such as eczema, dermatitis, rashes and certain types of acne

### AGG Observations

1. We frequently see companies that would like to make eczema claims for cosmetic products, as the manufacturers here did. Eczema claims are drug claims and cannot be made for a cosmetic product. A product for eczema relief can be sold under the OTC skin protectant monograph, but must contain colloidal oatmeal as the active ingredient and adhere to the other requirements under the monograph.

<sup>1</sup> <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm569211.htm> and <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm570017.htm>

<sup>2</sup> 21 U.S.C. § 321(i)

<sup>3</sup> 21 U.S.C. § 321(g)(1)

<sup>4</sup> 21 C.F.R. § 347.50(b)(4)

2. A product can be both a cosmetic and a drug, for example: a cleanser that also relieves eczema. Cleansing is a cosmetic claim and eczema is a drug claim. If you make both drug and cosmetic claims for your product, your claims and labeling must comply with both the regulations for drugs and those for cosmetics.
3. These are two more Warning Letters in a recent uptick in FDA scrutiny over similar claims. See, for example, “The First Cut is the Deepest: FDA Issues a Warning Letter to a Skincare Company for Marketing Unapproved New Drugs.”<sup>5</sup>

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<sup>5</sup> <http://www.agg.com/The-First-Cut-is-the-Deepest--FDA-Issues-a-Warning-Letter-to-a-Skincare-Company-for-Marketing-Unapproved-New-Drugs-06-16-2016/>

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