



## You Look Marvelous: Just Ask FDA Whether Beauty is in the Eye of the Beholder

Alan G. Minsk

Many of us remember Billy Crystal's "You Look Marvelous" one-liner from "Saturday Night Live," where the comedic routine frequently ended with "It's better to look good than to feel good." The Food and Drug Administration has a slightly different take for manufacturers -- it's ok to promote to look marvelous and to look good, but don't make any drug-like claims. And FDA seems to really mean it lately.

Since February 2015, FDA's Center for Food Safety and Applied Nutrition, which regulates cosmetics, has issued four Warning Letters to companies that crossed the cosmetic world line into the drug arena and, thus, were unapproved new drugs.<sup>1</sup>

FDA found that the topical skincare preparations were making therapeutic claims, such as "tightening neck cream," "wrinkle reducing treatment," "wrinkle reversing", "pigment control," and "DNA Eye Renewal" were drug-like and not approved or generally recognized as safe and effective.

CFSAN enforcement in the cosmetic area is not common. On occasion, the agency takes exception to anti-aging claims or issues an Import Alert for products that claim to be cosmetics but are labeled or promoted more as drug products. However, the recent increase in enforcement -- four warning letters by CFSAN and another one issued by a District Office, all in 2015 -- indicates that the agency is taking note.

### AGG Observations

In the movie, "This is Spinal Tap," where Crystal makes a cameo appearance, one of the main characters notes that "it's such a fine line between stupid and, and uh clever." So, too, here, there is a fine line between a cosmetic claim, such as beautifying and softening skin, and a drug claim, such as wrinkle reversing or reducing, or otherwise to treat a medical condition. The line is not merely market puffery; it's a regulatory line that, if crossed, can result in enforcement action. Such action can lead to relabeling of product, stopping sale of the product, and potential recall, to name a few consequences.

Companies must carefully review product labels, promotional claims, and other labeling materials to ensure regulatory compliance. While cosmetics might not seem high risk, the law is the law, and companies should use their internal promotional review committees, and outside counsel as needed, to evaluate whether a claim for a cosmetic product might tread into the drug world, whereby FDA, another government agency, such as the Federal Trade Commission, or competitors, to name a few watchers, could object.

You might look marvelous and beautiful until FDA gives you a regulatory black eye.

<sup>1</sup> While all of the letters are public, we will not identify any by name. See [www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440960.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440960.htm); [www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm434560.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm434560.htm); [www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm439818.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm439818.htm).

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