March 10, 2017

FDA Publishes New Warning Letters to Cosmetics Manufacturers Echoing Last Year’s Uptick in Scrutiny

Related Attorneys: **Sean Riley**, **Lauren Bragin**

Related Practices: **Litigation**

Reflecting a trend of increased scrutiny, on March 8, 2017, the U.S. Food and Drug Administration (FDA) posted two new Warning Letters providing important guidance on statements in cosmetics labeling and marketing amounting to the assertion of "drug claims." Keeping abreast of the advertising issues and buzzwords with which the FDA takes issue can help manufacturers avoid pitfalls, particularly since FDA warning letters often precipitate class action litigation. In 2016, the FDA issued 30 Warning Letters to cosmetic companies alone regarding what the FDA deemed "unapproved drug claims," up from just nine the prior year.

The types of claims addressed in these two newly posted Warning Letters, directed to Healthy Habits and Aegia Skin Care, LLC respectively, are on trend with the FDA's 2016 Warning Letters. They include claims regarding "curing," "treating," "healing," or "eliminating" various medical "conditions" (e.g. "scar shrinking," "rosacea," "eczema," "dermatitis," "acne," "psoriasis," "diabetic sores," "skin tags," and "skin infections"); "antibacterial," "antiseptic," "antifungal," "antimicrobial," and "anti-inflammatory" properties; and "stimulating," "improving," "boosting," or "promoting" "circulation," "cellular generation," or "natural skin regeneration."

First, in its December 16, 2016 Warning Letter to Healthy Habits the FDA focused on product testimonials and customer reviews. While your product may not make similar claims, this Warning Letter is a critical reminder of the FDA's position on testimonials posted on or promoted through digital platforms under your control: they are advertising claims for which you are ultimately responsible.

Notwithstanding Healthy Habits' disclaimer that "we are not medical doctors [and] we cannot address direct medical questions", the FDA advised that its product description as an "all-purpose" and "natural" "skin wellness formula" that "has been used effectively by people with a wide variety of skin problems..." was tantamount to unapproved drug claims under the Federal Food, Drug, and Cosmetic Act (FDCA). It is also evident from this Warning Letter that the FDA views language regarding what "customers tell us" as no different from any other type of advertising language. Thus, exercising caution when promoting product testimonials is important, as is proactive monitoring of comments on Facebook pages, Instagram posts, and Twitter feeds. While the FDA has not yet targeted social media accounts, the Healthy Habits Warning Letter foreshadows that the FDA may be moving in this direction.[1]

Similar to the Healthy Habits Letter, the FDA's February 17, 2017 Warning Letter to Aegeia Skin Care, LLC tracks issues identified in prior Warning Letters, but shifts its focus to concentrate on single ingredient claims. The tendency of manufacturers to highlight the reputed benefits of particular ingredients without making explicit parallel claims about the finished product has become a more widespread practice in recent years. It is now evident that these single ingredient claims are the FDA's latest target.[2] Indeed, it is apparent from this Warning Letter that advertising statements regarding ingredients associated with a specific product are viewed as equivalent to statements about the product itself. In particular, the FDA cited Aegia's claims regarding the benefits of tea tree oil, witch hazel, coconut oil, aloe vera, and vitamin E as evidence that Aegeia's products were "intended for use as drugs." Moreover, references by Aegia to what studies have shown about such ingredients, or the historical or alternative use of an ingredient (i.e. "has been known to") does not circumvent the application of the FDCA to the claims. While ingredient dossiers that substantiate the particular claims may be helpful to avoid false advertising allegations, they will not exempt such advertising claims from compliance with the FDCA.

In light of these developments, manufacturers should take care to avoid even ingredient-specific claims that could be construed by the FDA as crossing the line from cosmetic to drug.

---

[1] The FDA first took issue with claims made through product testimonials in its October 11, 2012 Warning Letter to Skin Biology, Inc., followed by an August 12, 2013 Warning Letter to Herbal Papaya, LLC, and a January 4, 2016 Warning Letter to Tibetan Herbal Balance, Inc. The Healthy Habits Warning Letter follows this trend.

[2] In July 2016, the FDA issued a number of warning letters which identified specific ingredient claims as problematic, among other issues. *See, e.g.* July 19, 2016 Warning Letter to Sevani Botanica, July 20, 2016 Warning Letter to Finally Pure, LLC, July 22, 2016 Warning Letter to Lavian Ltd., July 22, 2016 Warning Letter to Peter Thomas Roth Labs, LLC, July 28, 2016 Warning Letter to MiN New York. The Aegeia Skin Care Warning Letter suggests that FDA will continue to pursue these types of claims.

For more information, please contact the authors of this alert, Lauren Bragin, at 310.282.6252 or lbragin@glaserweil.com, or Sean Riley, 310.282.6265 or sriley@glaserweil.com, or your Glaser Weil attorney.

This article is intended for informational purposes only and is not intended as a substitute for legal counsel. It does not establish, and receipt of it does not constitute, an attorney-client relationship.
