

Cosmetics Under Fire: Tips To Avoid FDA Scrutiny

Law360, New York (November 30, 2012, 2:27 PM ET) -- The U.S. Food and Drug Administration has the cosmetics industry in its sights. Since September 2012, FDA has issued at least seven warning letters targeting the labeling and marketing of cosmetic products. And FDA has focused on companies at both ends of the spectrum — boutique houses with a handful of products and heavy hitters like Lancôme USA and Avon Products Inc.

In all of the letters, the FDA found fault with marketing claims that suggest the product has properties that are “intended to affect the structure or any function of the human body.” The FDA explained that these structure/function claims render the products “drugs” under section 201(g)(1)(c) of the Federal Food, Drug and Cosmetic Act (the Act). Because cosmetic products have not been approved as drugs, the structure/function claims violate the Act. The FDA also faulted several companies for making claims that the products were intended “for use in the diagnosis, cure, mitigation, treatment or prevention of disease.”

So what are the offending claims that render these products “drugs” according to FDA? Examples include:

- Lancôme’s Genefique, Renergie and Absolue product lines “boost[] the activity of genes,” “stimulate cell regeneration” and “rebundle collagen”
- Greek Island Labs’ Complexion Control Serum is “[c]linically proven to reduce breakouts and blemishes by 84 percent” with “bactericidal” and “anti-inflammatory properties”
- Andes Natural Skin Care’s BioSkinCare “activates ... fibroblast stem cells”
- Janson Beckett Inc’s DermaExcel 7 works “to block the nerve signals and ... inhibit[] the overproduction of catecholamines.”
- Bioque Technologies’ Serum Rejuvenate contains “penetrating liposomes and cell metabolism optimizers” that “activate[] production of collagen and elastane critical to rebuilding and maintaining healthy skin structure”
- Avon’s Anew Clinical Thermafirm Face Lifting Cream “formulated to fortify damaged tissue with new collagen” and “tighten the connections between skin’s layers”
- Skin Biology’s Emu Oil S for Skin produces “accelerated skin regeneration and also stimulated hair growth.”

The FDA concluded that the products “are not generally recognized among qualified experts as safe and effective for the above referenced uses” and cautioned all warning letter recipients that the violations identified were not “all-inclusive.” The FDA advised that recipients should “review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.” Recipients were given 15 working days from receipt of the letters to correct the violations and warned that failure to comply could result in enforcement action and potential seizure of the products.

FDA Scrutiny: The Threat of Regulatory Action

By issuing so many letters in such a short time frame, the FDA is sending a message: it is redoubling its efforts to ensure full regulatory compliance by the cosmetics industry. The FDA intends to closely monitor the labeling and marketing of cosmetics and will not tolerate claims suggesting that cosmetics favorably impact the structure and function of the body. Given the widespread use of structure/function claims, and the popularity of anti-aging products — which brought in \$3 billion in profits last year — additional warning letters are likely.

The Threat of Consumer Fraud Class Action Litigation

The risks to the cosmetics industry extend beyond FDA scrutiny. The FDA warning letters often attract lawyers, making these companies targets for litigation on a massive scale. Through advertising, consumer fraud lawyers can amass hundreds or thousands of plaintiffs, providing a springboard for protracted and extremely costly class action litigation. Plaintiffs will allege that consumers were defrauded into purchasing the product because of illegal marketing claims and trumpet those same FDA warning letters as proof that the marketing claims were deceptive under state consumer fraud statutes. Plaintiffs in these cases often seek to recover not only the costs of the product, but also treble, punitive and other damages.

The risk of consumer fraud litigation against cosmetics companies is not merely theoretical. On Sept. 21, 2012 — only three weeks after the first warning letter was issued — L’Oreal and subsidiary Lancôme were named in a proposed class action in Florida. See *Nino v. L’Oreal USA Inc.*, Case No. 1:12-cv-12362 (S.D. Fl.).

The lawsuit, which seeks to certify a nationwide class with a Florida subclass, alleges that the structure/function claims identified in FDA’s warning letter misled the public into purchasing anti-aging products. The named plaintiff piles on, taking issue with products other than those specifically mentioned by FDA. The plaintiff alleges that because “defendants utilize the same marketing schemes and promises for the entire Lancôme anti-aging product line,” the “claims of deceptive and misleading advertising/marketing apply to Defendants’ entire Lancôme anti-aging product line.” The plaintiff seeks disgorgement of profits, restitution and injunctive relief.

Then, on Oct. 29, 2012, L’Oreal and Lancôme were named in another proposed class action lawsuit (this one seeking to represent a class of California purchasers). See *Schwartz v. L’Oreal USA, Inc.*, Case No. 2:12-cv-5557 (N.D. Cal.). The plaintiff again relied on FDA’s warning letter, quoted it, and attached it as “Exhibit 1” to the complaint. This lawsuit is buoyed by an expert, allegedly retained “to conduct a good faith investigation in to the efficacy of Defendant’s claims.”

These companies were hit again on Nov. 5, 2012. See *Kallen v. L’Oreal USA, Inc.*, Case No. 12-9479 (C.D. Cal.). This lawsuit seeks to represent a class of California consumers who allegedly purchased Lancôme’s products and were led to believe that “the products could prevent, reduce, or reverse the signs of aging, including by manipulating biological structures.” In addition to seeking restoration of the monies spent on the products, the plaintiffs seek an order compelling Lancôme to “conduct a corrective advertising campaign.”

Avon was next. On Oct. 23, 2012, Avon was hit with a proposed nationwide class action (with a California subclass), alleging that it misrepresented its anti-aging products to consumers. See *Trujillo v. Avon Products, Inc.*, Case No. 12-9084, (C.D. Cal.). The plaintiff claims that Avon “disseminat[ed] false and misleading information via television commercials, Internet websites and postings, blast emails, radio media, blogs, video news, releases, advertisements, and the packaging” of the Anew product line, which induced her purchase of the products. The plaintiff seeks disgorgement of profits and restitution, injunctive relief and a corrective advertising campaign.

Yet another proposed nationwide class action was filed against Avon in California federal court on Nov. 9, 2012. See *Quinta v. Avon Products Inc.*, Case No. CV12-09629 (C.D. Cal.). Like its predecessor, this lawsuit seeks damages allegedly resulting from purchasers' reliance on marketing claims regarding the Anew product line. The plaintiff claims that Avon aggressively sought to capitalize on the growing "baby boomer population" by defrauding consumers about the efficacy of its products.

The number of lawsuits against cosmetic companies is likely to grow. Numerous plaintiffs' firms are advertising on a national scale for consumer fraud cases. Sophisticated class action lawyers may also attempt to export this theory to products and companies not covered by FDA's recent warning letters.

Strategies to Avoid FDA Scrutiny and Minimize Litigation Risk

Given the current regulatory and litigation environment, cosmetics companies cannot afford to take a sit-back-and-wait approach. Rather, companies should undertake in-depth litigation risk assessments of their product lines to identify and correct any labeling and marketing claims that might garner FDA attention or consumer concern. To better prepare for — and hopefully avoid — litigation, the risk assessment should seek to identify other issues likely to attract attention from the plaintiff's bar. The risk assessment should include detailed review of the following:

- Product labeling for structure/function claims, as well as claims that the product has use in the diagnosis, cure, mitigation, treatment or prevention of disease. The review should include all product packaging, including any claims printed on the product itself and on any product inserts.
- The company's website for potentially violative material. The FDA has already begun to review company websites and is likely to continue to do so. The risk assessment should include a review of any testimonials provided by product users that appear on the company websites. Even testimonials that are clearly attributed to product users have resulted in warning letters when they suggest uses of the product that would cause the product to be deemed a drug. Companies should consider whether the benefit of allowing users to post about their product experience is worth the risk of FDA scrutiny.
- All advertisement and marketing materials. In addition to TV, radio and glossy print advertisements, this review should scrutinize displays accompanying the product in stores and online advertisements, including those on social media sites. In 2009, the FDA issued warning letters to fourteen pharmaceutical companies based on allegedly inappropriate information in "sponsored links" that would pop up when a health term was entered into a search engine such as Google. Any structure/function claims in such links should be removed.
- Scientific support for any structure/function claims. This should include a review of testing done by third party efficacy testing houses, and consideration of additional testing that could be conducted to support marketing claims. Consumer fraud plaintiffs are likely to focus on the lack of "efficacy" of the product as it relates to the alleged deceptive labeling or marketing claim. For instance, plaintiffs are likely to argue that claims that a product "rebundles collagen" or "tightens skin" are not only false, but unsupported by scientific evidence. Companies that have engaged third-party testing houses will be ahead of the curve.

- Other “facts” about the product that could be exploited in litigation. For instance, the National Advertising Division of the Council of Better Business Bureaus (NAD) expressed concern with a CoverGirl mascara advertisement because the lashes in the photograph had been enhanced, even though the enhancement was clearly disclosed. The NAD concluded the advertisement was “misleading” and Procter & Gamble, the owner of the CoverGirl brand, permanently discontinued it. Plaintiffs may point to alleged photo-shopping of images used in advertising campaigns as evidence that companies engaged in a pattern of deception. Companies should work to identify areas likely to be targeted in litigation and be prepared — before litigation hits — to explain them.

By taking a proactive approach and assessing product risks on the front end, cosmetics manufacturers can significantly decrease the likelihood that they will find themselves facing an FDA warning letter or embroiled in consumer fraud litigation. Manufacturers that evaluate their products’ risks will be better positioned to defend themselves if regulatory action develops or litigation ensues.

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