

Cosmetic Regulatory Update: Key U.S. Issues for 2018

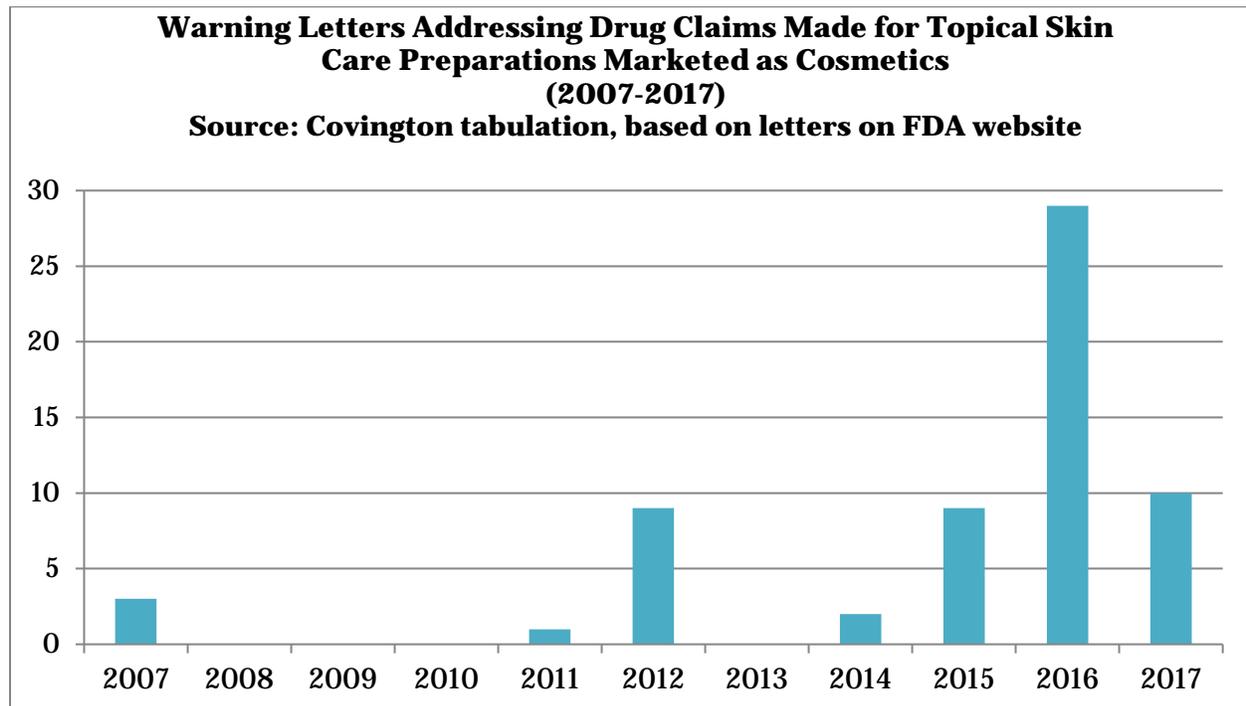
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Cosmetics

As we begin 2018, the cosmetic industry marketing products in the United States faces a range of legal and regulatory considerations – from labeling and marketing claims to ingredient safety and environmental issues. This alert for our cosmetic clients analyzes federal regulatory activities in 2017 and summarizes key issues to consider for 2018, including potential federal legislative developments and changes to certain state requirements.

Recent FDA Regulatory Activity

Warning letters. In 2017, FDA used warning letters as its primary regulatory effort relating to cosmetic products marketed in the U.S., issuing a total of 10 warning letters. This continues a pattern that FDA has followed for the past few years – FDA issued a record 29 warning letters in 2016 and nine in 2015. By contrast, between 2007 and 2014, FDA issued more than five warning letters in only one year, 2012, and issued no warning letters in 2008-2010 or 2013.



This trend could continue into 2018, and cosmetic marketers should be aware of certain categories of claims FDA has identified in recent warning letters as indicating an intended drug use (either because FDA asserts either that the product is intended to affect the structure or function of the body, or is intended for disease treatment or mitigation). In 2016 and 2017, FDA warning letters most frequently focused on claims relating to:

- Collagen production, stimulation, and/or synthesis (e.g., “help activate collagen,” “boost collagen production,” and “promote collagen synthesis”)
- Cell regeneration or renewal (e.g., “stimulates cellular regeneration,” “accelerates cell renewal,” “increases cell turnover,” “boost[s] natural cell metabolism,” and “encourages healthier skin replication”)
- Anti-inflammatory properties
- UV protection or prevention of sun damage (e.g., “protect skin against UV radiation,” “protect skin against UV damage,” “heal sun damage”)
- Enhancing or stimulating circulation
- Skin lightening effects, dark spot reduction, and redness reduction
- Anti-aging effects, including wrinkle reduction and fine line reduction.¹

Microneedling. Separately, last September FDA issued a [draft guidance](#) intended to assist industry in evaluating whether a microneedling product is a medical device or is solely intended for cosmetic uses. In the draft guidance, FDA advised that it will consider both product claims and product design/technical characteristics in determining a microneedling product’s intended use. The agency identified claims such as “Treats wrinkles and deep facial lines,” “Treats scars,” “Stimulates collagen production,” and “Treats cellulite and stretch marks” as claims that would indicate a microneedle product is intended for use as a device. Conversely, FDA identified claims such as “facilitate exfoliation of the skin,” “improvement in the appearance of skin,” “give skin a smoother look and feel,” and “give skin a luminous look” as claims that signal a product is intended for cosmetic uses.

In addition, FDA will evaluate whether needle length and arrangement, needle sharpness, and degree of control over the movement of needles facilitate penetration into living layers of skin (*i.e.*, beyond the stratum corneum). The fact that FDA issued this guidance could be a sign of FDA’s increased focus on microneedling products and other similar tools that are marketed for cosmetic uses.

Federal Legislative Developments

There continues to be meaningful movement in Congress on federal legislation that would reform FDA’s authority over cosmetic products. In May 2017, Senators Dianne Feinstein (D-CA) and Susan Collins (R-MA) introduced the [Personal Care Products Safety Act](#), and last October, Senator Orrin Hatch ((R-UT), who recently announced his retirement at the end of this Congress) introduced the [FDA Cosmetic Safety and Modernization Act](#). Both proposals would

¹ We have analyzed the full scope of claims that FDA identified in warning letters in the past few years and are happy to share that analysis upon request.

alter FDA's oversight of cosmetic products at the federal level in a number of ways, including through:

- serious adverse event reporting requirements;
- facility registration requirements;
- current good manufacturing practice requirements; and
- FDA review of ingredient safety.

Both of these bills have been referred to the Committee on Health, Education, Labor, and Pensions ("HELP Committee") in the Senate for further consideration, and the Committee is actively working on the issue.

In the House of Representatives, there have been several bills related to cosmetics in prior sessions of Congress, including [a discussion draft bill](#) that Representatives Frank Pallone, Jr. (D-NJ) and Leonard Lance (R-NJ) released in September 2016, as well as the [Cosmetic Modernization Amendments of 2017](#), which Representative Pete Sessions (R-TX) introduced in early 2017.

We note that Congress is expected to move a "must-pass" piece of FDA-related legislation in 2018 (related to reauthorization of FDA's animal drug programs ADUFA and AGDUFA), which could serve as a legislative vehicle for FD&C Act changes related to other issues (including cosmetics). Many relevant stakeholders are engaged in the legislative process around cosmetics reform, including individual cosmetic product companies and the Personal Care Products Council (PCPC) on behalf of its members.

Influencer Campaigns and FTC Action

The use of paid social media "influencers" to promote brands and products has taken digital advertising by storm. In recent months, the Federal Trade Commission (FTC) has shown – through guidance, warning letters, and cases – the importance of adequately disclosing the material connection between marketers and their social media influencers.

Most recently, the FTC brought its first [case](#) against individual social media influencers for allegedly engaging in deceptive practices when they endorsed an online gambling service they owned and operated without disclosing their ownership or that they had been compensated for promoting the website. Among other things, the [settlement](#) requires defendants to clearly and conspicuously disclose any material connections with an endorser or between an endorser and any promoted product or service, and to monitor their influencers for compliance.

This case demonstrates the FTC is following through with enforcement after its efforts to educate marketers about influencer marketing. Last spring, the FTC sent [educational letters](#) to 90 individual influencers who allegedly used insufficient disclosures on Instagram, calling out the specific posts that did not meet the FTC's standards for truth-in-advertising and reminding them of the FTC's Endorsement Guides. A few months later, the FTC issued [warning letters](#) to 21 of those influencers for allegedly continuing to fail to "clearly and unambiguously" disclose their connection to the brands or products they endorsed. The warning letters asked the influencers to disclose their material connections to the FTC and to describe the steps they will take to ensure adequate disclosures going forward.

Finally, the FTC recently updated its [guidance materials](#) to inform marketers of how to make adequate disclosures in a variety of social media. Together, the cases, letters, and guidance illustrate several important principles:

- Influencers must include a clear, non-misleading disclosure with their message whenever there is a “material connection” that reasonable consumers would not expect – even if the influencer was not paid. For example, if an influencer is given a product for free or invited to a free premiere of a movie, they should disclose that fact.
- Disclosures should not be ambiguous or confusing – for example, the FTC guidelines state that having influencers simply say “Thanks, [brand]” does not adequately convey the existence of a material relationship, as consumers may interpret that statement as merely a public “thank you” from a satisfied customer.
- Disclosures should be clear and conspicuous. Campaigns that involve Instagram stories or Snapchat should superimpose disclosures over the streams. Don’t assume that disclosure tools built into platforms such as Facebook, YouTube, and Instagram are sufficient.
- Be aware that the FTC views “tags,” “likes,” and “pins” as endorsements.
- Marketers must have reasonable programs in place to train and monitor members of their network. Companies must periodically audit their influencers and follow up with them in cases of noncompliance.

Upcoming Changes to Proposition 65

Cosmetic companies should also prepare to comply with recent changes to California’s Proposition 65 (“Prop 65”), the California law that requires a “clear and reasonable” warning for products that expose California consumers to chemicals that are listed by the state of California as causing cancer or reproductive toxicity in amounts that exceed safe harbor levels (established by the State or on a company’s own initiative). The new regulations make significant changes to the warnings that California has deemed compliant with the Prop 65 “clear and reasonable” warning requirement, including the following:

- **Warning statement.** The new regulations require that the warning identify, by name, at least one listed chemical in the product for each endpoint for which the warning is provided (*i.e.*, cancer and/or reproductive toxicity), and also require the warning to include the URL to the State’s Prop 65 website and a triangular yellow and black warning symbol (that can be downloaded [here](#)). The current regulations do not require the URL or warning symbol and allow for a warning to simply state that the product contains “chemical[s] known to the state of California” to cause cancer and/or reproductive toxicity, without naming a particular chemical. The new regulations also provide for use of a “shortened” warning and require the warnings to be in foreign language in addition to English in certain circumstances.
- **Internet retailers.** Online retailers will now be required to provide a Prop 65 warning for the product on the retailer’s website *in addition* to the warning that accompanies the product. The new regulations provide three options for providing such warnings: (1) provide the full warning on the product display page; (2) provide a clearly marked hyperlink on the product display page that says “WARNING” and links to the full warning; or (3) otherwise prominently display the full warning to the purchaser prior to completing

the purchase (e.g., provide the warning on a page before the consumer authorizes use of their credit card during the checkout process). The new regulations expressly state that a warning is not “prominently displayed if the purchaser must search for it in the general content of the website.”

The new requirements will go into effect on August 30, 2018. Until then, companies’ warnings can comply with either the existing or new requirements.

Covington & Burling LLP continues to monitor developments in legal and policy issues relevant to our cosmetic clients. In the coming months, look specifically for further updates on key considerations for cosmetic companies relating to the Nagoya Protocol, analysis of U.S. class action trends, key updates from other jurisdictions, and ongoing monitoring of U.S. legislative developments. If you have any questions concerning the issues discussed in this alert or other cosmetic regulatory matters, please contact any of the following attorneys or visit our [cosmetics practice](#) website:

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