

regulatory naturals

Regulating 'natural' in the US

In the US, 'natural' has not been a regulated term. But with the landmark Natural Cosmetics Act announced in November 2019, things may be about to change, as **Renée Appel** and **Tonya Esposito** of Seyfarth Shaw LLP explain

In 2019, the term 'natural' continued to appear on cosmetics and personal care products' labels. In 2020, rising in the ranks, however, were 'sustainability' and 'clean', among other words connoting purer ingredients and product origin.

Such product philosophies and trends will be tested in a time when nearly everyone's focus has shifted to anti-viral and antibacterial amidst the Covid-19 pandemic. Indeed, the first products to leave shelves barren were chemical-enriched hand sanitisers and wipes.

Are people willing to cast away natural in the wake of a pandemic, or are people's enhanced safety concerns going to promote a desire for 'cleaner' products?

REGULATORY OVERSIGHT

In the US, 'natural' is not a regulated term in cosmetics. That is, you can search the laws and regulations governing cosmetics, but you will not find the term 'natural' defined. It is unlike 'organic', which is regulated by the U.S. Department of Agriculture and requires that a product labelled organic consist of 95% organic ingredients (excluding salt and water).

Additionally, 'made with organic xxx' may be used in connection with products containing at least 70% organically produced ingredients (excluding salt and water). In the US, there are no equivalent parameters for the word 'natural'.

The principal law governing cosmetics in the US is the Food, Drug & Cosmetic Act (FD&C Act). The FD&C Act defines cosmetics by a product's intended use: "for cleansing, beautifying, promoting attractiveness, or altering the appearance" of the body, other than soap.

Under the FD&C Act, the U.S. Food and Drug Administration (FDA) regulates cosmetics and ingredients, but there is no pre-market

How will demand for naturals fare in the aftermath of the Covid-19 pandemic?



approval, except for colour additives.

This means the FDA does not evaluate cosmetic products before they are sold to consumers.

In addition, there are no testing requirements. But cosmetics manufacturers are required to substantiate product and ingredient safety. The FDA has stated that "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information".

Along with ensuring the safety of products, cosmetics companies are responsible for properly labelling them. Product labelling cannot be false or misleading. The FDA and U.S. Federal Trade Commission (FTC) jointly regulate compliant labelling.

The FTC's regulatory authority stems from the Fair Packaging and Labeling Act (FP&L Act) and the Federal Trade Commission Act (FTC Act). Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce". 'Unfair' practices are defined as



those that “cause... or [are] likely to cause substantial injury to consumers”.

Section 12 proscribes the dissemination of any “false advertisement” for food, drugs, devices, services, or cosmetics – “an advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer’s purchasing decision”.

In the absence of any formal definition of ‘natural’ in cosmetics, regulatory actions, brands and retailers have helped to develop the meaning of the term, albeit not uniformly.

ACTIONS SHAPING ‘NATURAL’

Within the US regulatory framework, in 2016, the FTC entered four settlement agreements with cosmetic and personal care products manufacturers regarding purported natural products.

In each of the cases, the companies advertised products as natural, but the products contained at least one synthetic ingredient, which the FTC deemed misleading. In announcing these actions, the FTC commented, “‘all natural’ or

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‘100% natural’ means just that – no artificial ingredients or chemicals”.

That same year, the FTC brought an administrative action against a company selling sunscreen marketed as ‘all natural’ and advertising on its website that it “uses only the purest, most luxurious and effective ingredients found in nature”. The FTC held that the claims were also misleading because at least 8% of the product was dimethicone, a synthetic ingredient. Relying on its authority from the FTC Act, the FTC found that these companies violated Section 5 by falsely advertising their products as natural.

Also in 2016, the National Advertising Division (NAD) of the Council of Better Business Bureaus (CBBB), a non-governmental entity that monitors national advertising in all media, recommended that a company discontinue ‘natural’ and ‘naturally’ claims for its ‘naturally dry’ antiperspirants because they contained aluminium.

The NAD took the position that “claims that a product is natural when the active ingredients are not is a different matter than making a ‘natural’ claim where most ingredients, including all active ingredients, are natural and a small percentage of the product ingredients are not natural”.

In a prior case involving the same manufacturer but a different product, NAD found the “pure simple ingredients from nature” claim was supported where all the active ingredients were naturally sourced, but approximately 1% of the product was a non-natural emulsifying agent. Between these matters, the NAD seemed to suggest that ‘natural’ is fluid and its accuracy depends on the active ingredients as compared with the entire composition of the product.

In yet another forum, US courts have also been forced to tackle the meaning of ‘natural’, while others have skirted the issue altogether, staying cases until the FDA sets forth a standard. These cases are led by plaintiffs’ counsel suing companies in class actions for false representations, unfair sales practices and consumer protection violations based on ‘natural’ claims.

Courts, however, are “split as to whether the issues presented by... ‘all natural’ claims are more within the conventional expertise of judges, or whether they involve technical or policy considerations within the FDA’s particular field of expertise”. At least one court has stated, “the term ‘natural’ is an affirmative claim about a product’s qualities and is, therefore, not ‘an exaggeration or overstatement expressed in broad, vague and commendatory language’”.

Other courts have echoed the position of the FTC, finding: “It is not unreasonable as a matter of law to expect that a product labelled ‘natural’ or ‘all natural’ contains only natural

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ingredients. This is true even if mildly qualifying language or synthetic ingredients are listed on the product's packaging."

Another court stated, "a reasonable consumer could understand the statements '100% natural' or 'all natural' or 'natural' together with other terms implying 'all natural' to mean that a product does not contain any non-natural ingredient". Other than words, courts have also considered pictures, holding that "the depictions of leaves and flowers, statements emphasising natural ingredients like woodland pine or ginseng... further suggests... ingredients are natural". Natural-based litigation continues to permeate US dockets, leaving open further interpretations.

NATURAL COSMETICS TODAY

Although the FDA has not defined 'natural' in the context of food, it has indicated that 'natural' means nothing artificial or synthetic (including all colour additives, regardless of source) has been included or added.

In a March 2018 speech, then-FDA Commissioner Scott Gottlieb acknowledged that in late 2015, the FDA sought feedback from consumers and the industry on whether the FDA should regulate the word 'natural'.

In a letter addressed to then-Congressman David Valadao, dated 19 December 2018, Gottlieb added that the "FDA is actively working on this issue and in 2019, FDA plans to publically communicate next steps regarding Agency policies related to 'natural'".

Through its enforcement actions, however, the FTC has adopted the definition of 'natural' as used by the FDA in foods, insisting that products claiming to be 'all-natural' or '100% natural' should not contain artificial ingredients or chemicals. By contrast, the NAD has indicated that 'natural' can be used where a small percentage of the product ingredient is not natural.

Given the lack of consistency, manufacturers are left on their own to shape what natural means. In November 2019, seeking to address this issue, US representative Sean P Maloney (NY-18) introduced the landmark Natural Cosmetics Act (the Bill), which would create clarity by defining the terms 'natural' and 'naturally-derived ingredient' as they are used in personal care products.

Under the Bill, 'natural' means a product consisting of at least 70% natural substances (unprocessed ingredients) and 'naturally-derived ingredient', which means the starting material is of mineral, plant, microbe or animal origin, or otherwise derived from a plant feedstock.

To maintain accountability, the Bill requires suppliers to conduct Carbon-14 testing, which they must submit to manufacturers. The Bill would also authorise the government to issue a cease distribution order, public notice on the

FDA website and voluntary recall authority of any product deemed misbranded under this act.

Other legislation under consideration by Congress include the Personal Care Products Safety Act (S. 726) (Sens. Dianne Feinstein (D-CA) and Susan Collins (R-ME)), Cosmetic Safety Enhancement Act of 2019 (H.R. 5279) (Rep. Frank Pallone, Jr. (D-NJ)), and the Safety Cosmetics and Personal Care Products Act (H.R. 4296) (Rep. Jan Schakowsky (D-IL)).

These bills do not address 'natural' cosmetics per se but task the FDA with reviewing safety data on cosmetic ingredients. On 4 December 2019, a Congressional subcommittee on Health of the Committee on Energy and Commerce held a hearing entitled, 'Building Confidence by Empowering FDA to Improve Cosmetic Safety', procuring testimony from the FDA and industry members regarding issues addressed by this proposed legislation. Points raised included (i) enabling the FDA with stronger enforcement mechanisms, including the ability to issue mandatory recalls and (ii) establishing requirements for registration and testing that may vary between smaller indie companies and larger cosmetic conglomerates.

The foregoing cosmetic legislation may be too little too late. In light of the Covid-19 pandemic facing the world, legislation for cosmetics is taking a backseat while Congress focuses on relief packages to keep the country afloat. Similarly, the FDA is concentrating efforts on tackling the coronavirus.

Separate from the urgency presented by Covid-19, cosmetics brands and stores alike have also shifted a focus from mere natural product labelling to clean marketing campaigns that are embedded in branding. Retailers too have followed the trend employing 'clean' programmes, identifying certain products as green or 'clean' based on the retailers' independent determination. Generally, to qualify as 'clean', or whatever naming convention a store is using, the products need to be 'free of' certain ingredients.

Consumers would benefit from greater consistency and clarity across retailers and brands. For now, each maintains its own 'toxic' ingredient list and varying interpretations of the term 'clean'. Congress can eliminate the confusion by setting forth standards for 'natural', 'clean', 'green' and other marketing verbiage that has taken on a premium in the industry (ie consumers will pay more for perceived safer, healthier products).

There needs to be additional education to consumers so that they can understand which ingredients are harmful and which others are subject to misinformation●

References

Full references for this article can be found online at cosmeticsbusiness.com.

Under the Natural Cosmetics Act, 'natural' means a product consisting of at least 70% natural substances and 'naturally-derived ingredient'

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