

Did 2016 Come to a “Natural” Conclusion?



By Ronie Schmelz

As 2016 came to a close, food, nutritional supplement and cosmetic companies that sell “natural” products remained targets of and vulnerable to regulatory enforcement actions and consumer class actions. While 2016 saw some regulatory activity surrounding the terms “natural,” “all natural” and “100 percent natural,” the year ended without the issuance of regulations or guidance on how these terms should be defined.

As the new administration assumes office, bringing with it an uncertain regulatory environment, it remains to be seen what action, if any, the U.S. Food and Drug Administration (FDA) will take in this area, among others. This uncertainty demands that companies be ever more vigilant in monitoring not only regulatory activity, but the scores of pending lawsuits and judicial decisions they will spawn, which, in the absence of regulatory action, will inform the debate over the “reasonable consumer’s” expectations when purchasing a “natural” or

“all natural” product. In the absence of regulatory activity, companies may also want to consider pursuing certification from the myriad of private organizations that certify “natural” products. If marketed properly, selling products with these “seals” of approval could provide some cover and defense to consumer class actions.

Here, I recap the actions taken in 2016 by the FDA and Federal Trade Commission (FTC) in this “natural” area and highlight several third-party certification programs that offer certification of natural products.

FDA—To Define or Not Define?

As of December 2016, the FDA has considered use of the term “natural” only in the food context. Although the agency has yet to define the term, it has adopted the following longstanding policy concerning use of the term in human food labeling: “natural” means that “nothing artificial or synthetic (including all color additives regardless of source) has

been included in, or has been added to, a food that would not normally be expected to be in that food.

In 2016, as the number of “natural” food offerings has grown and in direct response to requests from consumers and courts, the FDA asked for information and public comment on the following questions:

- Whether it is appropriate to define the term “natural;”
- If so, how should the agency define “natural;” and
- How should the agency determine appropriate uses of the term on food labels?

At the close of the public comment period, the FDA had received a total of 7,690 responses. There is no indication how long it will take the agency to consider these comments or when we can expect the agency to announce whether it has decided to define the term “natural” and, if so, how. Even if a definition is forthcoming, it will likely be limited to the labeling of food, thereby leaving nutritional supplement and cosmetic

companies to extrapolate how the definition might apply to their products.

FTC—"All Natural" means no synthetic ingredients, but "Natural" is not the same as "All Natural"

While the FDA has taken baby steps to address the debate over "natural," the FTC has taken more significant strides by pursuing actions against companies that market "all natural" and "100 percent natural" products.

Last summer, the FTC announced it had approved settlements with four companies that market products as "all natural" or "100 percent natural" when they contain artificial ingredients. Upon announcing the settlements, FTC Bureau of Consumer Protection Director Jessica Rich stated that "'[a]ll natural' or '100 percent natural' means just that—no artificial ingredients or chemicals."

Subsequently, in response to a public comment, the FTC rejected the notion that the term "natural" means the same thing as "all natural," stating it did not have evidence that consumers necessarily interpret "natural" to mean "all natural" or having no synthetic ingredients.

In December 2016, the FTC issued an order against California Naturel, Inc., finding that the company's marketing of its Sunscreen SPF 30 product as "all natural" was false and misleading since it contained dimethicone, a synthetic ingredient. In reaching its findings, the FTC relied on claims made on the company's website, including a description of the sunscreen as a "soft, luxurious and non-oily all-natural sunscreen," which "uses only the purest, most luxurious and effective ingredients found in nature." According to the FTC, these claims, together with the product packaging, plainly conveyed to reasonable consumers that every ingredient in the product is natural. The FTC rejected the company's claim that a disclaimer added to the bottom of its webpage, which was not visible without scrolling down, sufficed to change the net impression conveyed to consumers.

The settlements and the commission's order in California Naturel prohibits the companies from misrepresenting: 1) the ingredients or compo-

sition of their products; 2) stating a product is "all natural" or "100 percent natural" when it contains any natural or synthetic ingredient or component; and 3) the environmental or health benefits of a product. The companies must also have competent and reliable evidence to support any of the claims they make about their products. Companies marketing products as "all natural" or "100 percent natural" are well advised to review their product claims and make sure product dossiers contain similar evidence to substantiate their claims.

In response to a public comment, the FTC rejected the notion that the term "natural" means the same thing as "all natural," stating it did not have evidence that consumers necessarily interpret "natural" to mean "all natural" or having no synthetic ingredients.

Non-governmental Options: Private "Natural" Certifications

There are literally hundreds of "green" symbols on the market certifying everything from bubble bath, furniture and household appliances to surfboard wax and cleaning goods. Some are issued by organizations with missions to protect the earth, preserve the environment and conserve energy, while others focus on safeguarding the health, safety and well being of humans and animals. As

food, nutritional supplement and cosmetic companies await a regulatory definition of "natural," some have sought to fill a void by pursuing "natural" certifications by third parties. While passing certification and placing a seal on a product is not an absolute defense to a consumer challenge, if marketed properly, it could help defeat false advertising and misrepresentation claims. Listed below are three organizations with certification programs and brief descriptions of the criteria they impose.

1. Natural Products Association (NPA)

NPA, the nation's largest and oldest nonprofit dedicated to the natural products industry, has developed a Natural Standard and Certification for Personal Care Products (the "Standard"), which sets forth detailed requirements for obtaining an NPA Natural Certified seal. Among other criteria, to obtain the seal, "natural" products must:

- Be made with at least 95 percent natural ingredients—excluding water;
- Contain only synthetic ingredients specifically allowed by NPA and be environmentally friendly products that are nurturing to people and as harmless as possible to the earth;
- Contain ingredients generally recognized as safe (GRAS) and come or be made from a renewable resource found in nature (Flora, Fauna, Mineral); no petroleum compounds allowed;
- Contain synthetic non-natural ingredients only when there is no readily available natural alternative ingredient and only when there are no suspected human health risks as indicated by peer-reviewed third-party scientific literature; and
- Not include certain prohibited ingredients, including those that incorporate synthetic silicone or petroleum compounds.

NPA developed an Illustrative List as a reference document that lists ingredients that meet the NPA definition of "natural" or are permitted synthetics. To obtain an NPA "natural" certification, companies must also use a majority of recyclable and post-consumer recycled content in their packaging and at least 60 percent of their product line must qualify for NPA certification before the organization will certify any products.

2. EcoCert Greenlife SAS

This international organization was the first to develop standards for natural and organic cosmetics. Its standard for certifying "natural" cosmetics includes these mandates:

- A minimum of 50 percent of all plant-based ingredients in the formula and a minimum of 4 percent of all ingredients by weight must come from organic farming;
- Ingredients must be derived from renewable resources, manufactured by environmentally friendly processes—products cannot contain GMO (genetically modified organism), parabens, phenoxyethanol, nanoparticles, silicon, PEG, synthetic perfumes and dyes, or animal-derived ingredients (unless naturally produced by them; e.g., milk, honey, etc.); and
- Biodegradable or recyclable packaging must be used.

3. Whole Foods Premium Body Care Seal

Whole Foods Market, perhaps the most influential national retailer of

natural products, has its own standards that companies must meet before the company will sell their products. For example, Whole Foods has identified more than 75 ingredients common in conventional body care products that it does not allow in any of the products sold in its markets. It also developed its own Premium Body Care standards that impose strict criteria for ingredients, which must come as close to nature and be as minimally processed as possible, and have little environmental impact during manufacturing and when released into the environment. To date, the company has identified more than 400 ingredients it deems unacceptable for the Premium Body Care seal, including parabens, polypropylene and polyethylene glycols, sodium lauryl and laurel sulfates. It allows only natural essential oils or components of natural essential oils for use as fragrances and sells only sunscreens that create a physical barrier on the skin (zinc oxide and titanium dioxide), as opposed to chemical sunscreens (such as oxybenzone and octyl

methoxycinnamate). There are more than 2,500 products bearing the Premium Body Care seal.

Looking Ahead

As we welcome 2017, the prospect of a regulatory resolution to the "natural" problem seems distant. The time may have come for us to work together and with third parties to try and stymie the onslaught of legal action that our "natural" industries face. Here's to a "naturally" prosperous and safe 2017. **NIE**



Ronie Schmelz is an attorney with Tucker Ellis LLP in Los Angeles, CA. She counsels clients on litigation-avoidance strategies and ensuring compliance with regulations enforced by the U.S. Food and Drug Administration (FDA), Federal Trade Commission (FTC), and other regulatory agencies. She can be reached at ronie.schmelz@tuckerellis.com.

FEELING TRAPPED BY YOUR...
CURRENT MANUFACTURER?



**FREEDOM AWAITS YOU
WITH GENEREX LABS**

**Call Now To Get Your
FREE Quotes On...**

- Capsules
- Creams
- Powders
- Softgels
- Sublinguals
- Tablets
- Wafers
- Custom Formulations
- Turn Key Packaging
- Bottles
- Blister Packaging
- Packets

**We guarantee to beat
any competitors price!**

For more information, please contact
info@generexlabs.com
1915 Trade Center Way, Naples, FL 34109
Phone: 239-592-7255 • Fax: 888-434-9146
www.GenerexLabs.com

Go to www.niemagazine.com/generexlabs for info about this advertiser