

# A Legal Look at the Definition of 'Clean Label'

by Steven Shapiro

## INSIDER's Take

- While FDA doesn't have a legal definition for "clean label," legal activities can help brands navigate terms such as "natural," "no artificial ingredients" and others.
- FDA's position is that any ingredient used to color a food must be labeled as an "artificial color," even if the ingredient comes from a natural source.
- The "clean" movement also applies to packaging, where FDA has defined the amount of slack fill that can be in the product's container.

### In the legal profession, we look to the law to define popular claims.

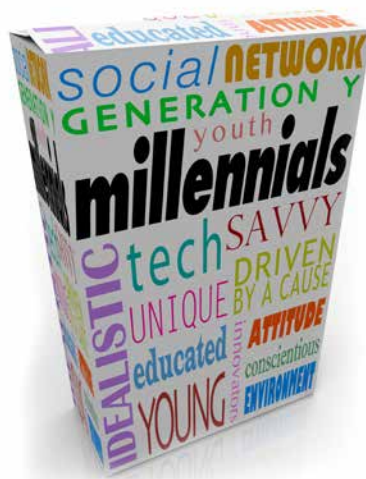
Has Congress passed a law? Has FDA promulgated a regulation? Has FTC brought an enforcement action? Is there a pending class action lawsuit? When it comes to "clean label," none of this seems to be happening. Rather, clean label is a movement following perceived consumer perception. Millennials like their labels and one would assume, their food and dietary supplements, "clean," whatever that term may mean. As Millennials are an increasingly powerful consumer group with disposable income to spend on purchases, industry is looking to satisfy their needs and desires.

The most obvious part of the clean label trend is a reduction in the number of ingredients in products, particularly ingredients with long or unidentifiable names, those that are perceived to be artificial or synthetic, and those that serve no nutritional or functional benefit. For many dietary supplements, this means a reduction in the number of "other ingredients" or the removal of such ingredients entirely where possible.

Companies considering the clean label trend are asking, "Can we make the capsule smaller to avoid the need for fillers? How do we press tablets without binders? Do we need excipients?" Obviously, these questions intrigue formulators and sometimes confound manufacturers. Concerned clean label consumers do not want to see ingredients that appear to be wasteful, damaging to the environment or serve no benefit in terms of why they are purchasing the product.

Can the product be shelf stable without preservatives? Preservatives, which are required to be identified as such pursuant to FDA regulations, can be viewed as "bad," and current FDA guidance on "natural" claims prohibit claiming a product is natural if it contains preservatives (even if the ingredient itself is natural).

What about ingredients intended to act as colorants in a product? Companies can claim colors as "natural," but will FDA agree? FDA's long-standing position is that any ingredient added with the intent to color a food, even if the ingredient itself is natural, is an "artificial color,"



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and may need to be labeled as such; and the agency does not recognize the term “natural color” (21 CFR 101.22(k)). Therefore, claims of “natural colors” raise issues and one cannot claim, “no artificial colors,” if a product contains any ingredient intended to act as a colorant.

When it comes to flavorings, one can assume anything identified as an “artificial flavor” would be best avoided on a clean label, and even “natural flavors” may be called into question when the “real” fruits, spices or other tasty ingredients can be used instead.

The ingredient list for a clean label should be short, to the point, with recognizable ingredients and as few chemical-sounding names as possible, although none would be preferable.

As to the popular claims on so-called “clean labels,” some are clearly defined and others are questionable. Lack of certainty can lead to greater risk of enforcement or a consumer class action lawsuit.

Clearly, organic products, particularly those with the USDA seal, are favorably viewed. Organic claims are backed by a clear standard, and clean label consumers know such products go through a certification process with the certifier identified on the label, before claims can be made.

Some consumers also value products with “gluten free” claims, and any company considering using this claim must be certain they understand 21 CFR 101.91, which sets forth FDA’s specific requirements for compliance in this area.

“Fresh” is another potential clean label claim that some may not realize is defined and regulated by FDA. A “fresh” claim, according to 21 CFR 101.95, “suggests or implies that the food is unprocessed, means that the food is in its raw state, and has not been frozen or subjected to any form of thermal processing or any other form of preservation.” Likely, few processed dietary supplements would be able to meet this claim.



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Everyone seems to be in favor of “natural” products, and many consumers are willing to pay a premium for them. In 1993, FDA stated in a Federal Register notice that:

FDA is not undertaking rulemaking to establish a definition for “natural” at this time. The agency will maintain its current policy (as discussed in the general principles proposal (56 FR 60421 at 60466)) not to restrict the use of the term “natural” except for added color, synthetic substances and flavors as provided in §101.22. Additionally, the

agency will maintain its policy (Ref. 32) regarding the use of “natural,” as meaning 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 the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in §101.22—58 Federal Register 2302 (January 6, 1993).

How does one define natural in terms of nothing artificial or synthetic? Isn't that rather circular? Clearly, a botanical must be natural—or is it? What if it is a genetically modified organism (GMO)? Clean labels would tend to avoid GMO ingredients. What if the botanical is highly processed so only a few constituents remain? Where is the line drawn? Ill-advised natural claims have drawn the attention of classaction plaintiffs, although recent reports seem to indicate the tide of those lawsuits may finally be diminishing. Anyone considering a “natural” claim must confirm it is accurate and limited to what can reasonably be established as natural. “All natural” or “100% natural” may be difficult to defend if challenged.

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In 2015, FDA finally agreed to collect comments on the use of the term “natural” in the labeling of foods, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. FDA opened its proceeding after receiving a number of citizen petitions and requests from federal courts involved in private party litigations (class actions). The comment period closed in early 2016 with FDA having received [7,690 comments](#) in Docket FDA-2014-N-1207. It remains to be seen whether FDA will regulate natural claims, or whether it will not take any further action.

GMO-free claims are another popular clean label trend. The National Bioengineered Food Disclosure Standard was enacted on July 29, 2016. The law provides for the Agricultural Marketing Service (AMS) of USDA to have two years to establish a national standard and the procedures necessary for implementation. AMS has recently released a list of [30 questions](#) for consideration by interested stakeholders. USDA has stated it will use this input in drafting a proposed rule. So, if GMO and bioengineering claims are a concern, a company should consider providing the requested input.

FDA views many “healthy” claims as implied nutrient content claims, pursuant to 21 CFR 101.65(d). Most of the current requirements for making a “healthy” claim focus on fat content, which proved an issue for Kind LLC, and its marketing of “healthy” bars containing nuts; the company receiving a [warning letter](#) on March 17, 2015.

Kind argued that considering the proven health benefits provided from consumption of nuts, the presence of some fat should not be a prohibiting factor in denying use of the word “healthy.” FDA agreed, and in September 2016 issued [“Guidance for Industry: Use of the Term ‘Healthy’ in the Labeling of Human Food Products”](#) and opened a docket for submission of comments concerning the issuance of a revised regulatory definition of “healthy.”


Several other claims that appear on labels are not well defined, and must be used with care to ensure their use is adequately substantiated should there ever be an issue, such as a consumer class action. Claims that fall into this category include, “raw,” “artisanal,” “handmade,” “wholesome” and “nutritious.”

The “clean” movement is not limited to labels; it also can apply to packaging. A clean package is one that should not appear to be wasteful. FDA has a regulation that addresses misleading containers, 21 CFR 100.100, most often referred to as “slack fill.”

According to the regulation, a container that does not allow the consumer to fully view its contents is considered misleading if it contains nonfunctional slack-fill. Slack-fill is defined as the difference between the actual capacity of a container and the volume of product contained therein. FDA does provide for exceptions for empty space when necessary to protect the contents of the package (e.g., some air to protect potato chips from crushing); the requirements of the machinery used in processing; unavoidable product settling during shipping and handling; the need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food), where such function is inherent to the nature of the food and is clearly communicated to consumers; when the package is a reusable container or gift package; and finally, when the package size is necessary to accommodate required labeling or tamper prevention features. Slack-fill issues have recently risen in prominence due to a spate of consumer class actions.

Finally, clean label customers are often concerned about the recyclability of packaging, and the “cleanest” packages are those that can be recycled. Claims concerning the recyclability of packaging are regulated by FTC, which has issued what is generally referred to as the [“Green Guides”](#) for making such claims.

FTC’s Green Guides caution marketers not to make unqualified environmental benefit claims because “it is highly unlikely that marketers can substantiate all reasonable interpretations of these claims.” Rather, FTC believes marketers should focus consumers on the specific environmental benefits they can substantiate, noting to marketers that explanations of specific attributes, even when true and substantiated, will not adequately qualify general environmental marketing claims if an advertisement’s context implies other deceptive claims.

So in the end, clean labels are statements of food that are simple and understandable, with as few technical or artificial ingredients as possible, presented in packaging that is not viewed as wasteful and can be readily recycled. 



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