NATURAL PRODUCTS INSIDER®

# Understanding Clean-Label Dietary Supplements

by Michael Finamore

**The "clean-label" movement in the** supplement industry, which initially had its genesis with the health-conscious consumer, has crossed over into mainstream thought and presents an opportunity to expand the market. Typically, a consumer is looking for a clean-label product to indicate some of the following: simple ingredient names, minimal use of manufacturing aids, inclusion of natural ingredients, and being free from GMOs (genetically modified organisms), gluten, allergens, and artificial or synthetic components. In a sense, they hope their chosen product remains void of the ingredients they feel to be "unnecessary" and take away from the clean/natural purpose for which they are actually buying the product. Understanding how to define and capitalize on this market may hold the keys to the future growth of the supplement industry. More importantly, it may help keep customers from searching for these answers in different food or natural sources, which would reduce the supplement industry's presence in the market.

What or who defines a true "clean-label dietary supplement?" FDA has not defined "clean label," just as it has not defined "natural." The industries impacted, primarily food and dietary supplements, have been left to come up with their own definitions. In many cases, the meaning of clean label is now left up to the individual brand owners or manufacturers, which can cause confusion among consumers and threatens to dilute the opportunity to drive improved products to market.

In the world of dietary supplements, there are variations on clean label. Some suppliers believe their label is clean if the product contains only "natural," raw materials. Others believe they have achieved a clean label if the ingredients are GMO-free. A third school of thought is a product has a clean label if there are no excipients used to produce the product. However, before industry can clear up the issue, we believe it's important to understand the consumer's perception when shopping for these items, and to recognize the ability of certain manufacturers to deliver products that meet or exceed those expectations.

There are a few accepted challenges faced by the brand owner and the contract manufacturer when developing such products:

- Find natural, non-GMO ingredients;
- Source organic ingredients when available;
- Keep products allergen/gluten-free;
- Correctly manufacture products without traditional manufacturing aids (excipients/non-active ingredients); and
- Minimize use of additives and fillers.

Making a dietary supplement that is all-natural represents its own challenges. With no clear definition for natural, it is left up to the contract manufacturer and brand owner to determine what ingredients will comprise a natural product, and how to reconcile those choices with the differing positions of the consumer market. Thus, it will take time to reach consensus between consumers and brand owners as to what constitutes a clean-label product with only natural ingredients.

Finding dietary supplement ingredients that are truly GMO-free is a challenge. The supplement manufacturer needs to have a robust sourcing and quality system, as well as great relationships with quality suppliers to verify all characteristics of the ingredients. Although there are several certification programs available for identifying non-GMO ingredients, many of the raw materials used in dietary supplement production don't have sufficient pedigree to demonstrate they are non-GMO.

The same is true for finding and sourcing organic raw materials. There are strict definitions as to what qualifies as an organic raw material. As we know from our local grocery stores, while there are now a number of organically grown options, they also come with a premium price and aren't always available. Since the availability and predictability of organic items at an ingredient level has not yet reached full commercialization, the contract manufacturer must be aware of these shortcomings when choosing a supplier.

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The contract manufacturer has to work closely with the vendors to synchronize paperwork and production to ensure it is providing the highest-quality products to its customers.

Fortunately, the issues surrounding gluten- and allergen-free products have been so prominent over the past few years that many raw material suppliers have already addressed these issues, which makes sourcing gluten-free or allergen-free raw materials easier, eliminates confusion in the marketplace and allows an expanded product range of options for consumers.

However, these ingredients—while used throughout industry and approved by FDA—have come under additional scrutiny by consumers wishing for an alternative. In response, new excipients made from rice products have been developed as clean-label alternatives to stearic acid and magnesium stearate. The use of these rice-based, organic and non-GMO items allows the formulation of products with a minimal use of traditional manufacturing aids. This also provides the consumer with a clean-label alternative to other products in the market.

**Quality contract manufacturers also must be aware of "hidden" ingredients, such as additives and fillers, which are sub-components of chosen ingredients.**

Nonetheless, there are times that, despite customer or consumer demands, manufacturing aids (excipients/non-active ingredients) are required to be used to correctly make a product. Not only must the formula be designed to fit into its dosage form, but GMPs (good manufacturing practices) require the product to be the outcome of a repeatable manufacturing process and to have it meet all testing requirements for its stated shelf life. In those cases, the use of small amounts of specialty ingredients (like silica or microcrystalline cellulose, for example) has been required in the past.

Quality contract manufacturers also must be aware of "hidden" ingredients, such as additives and fillers, which are sub-components of chosen ingredients. The most common example occurs with botanical extracts, which almost always have an otherwise-benign carrier material such as maltodextrin added to assist with manufacturability. When investigating the ingredient for clean-label compliance, increased scrutiny is required. For instance, in this case, the contract manufacturer would need to certify that the maltodextrin is gluten-free, and also needs to determine whether it's GMO-free before using the product.

The contract manufacturer needs to have a robust sourcing and quality system before it can truly offer a clean-label item. Along those lines, it is possible to harmonize consumer expectations with industry practices to achieve a clean-label dietary supplement today if the following conditions are met:

- Use of natural ingredients;
- GMO-free raw materials;
- Allergen-free;
- Gluten-free certification;
- Simplified naming on the Supplements Facts Panel; and
- Elimination of unnecessary traditional manufacturing aids.

Until these considerations mature and become part of routine/mainstream dietary supplement manufacturing, each one may have a cost or engineering premium associated with it. As usual, it will be up to the brand owners and market conditions to determine the scope and extent of their clean-label initiatives. With the additional attention and opportunity the clean-label movement affords our industry, all parties should be prepared to address these considerations in the near future.

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