

The Complexity of the Inflammation Claim

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Inflammation is the foundation of the innate human healing response. But science has shown that inflammation has a split personality—one side supports health, the other wreaks havoc. And for dietary supplement companies, inflammation can also cause headaches—the regulatory kind. But let's start with the science.

The body uses inflammation to respond to infection, injury or irritants such as dust and pollen. Inflammation increases blood flow, immune activity and tissue repair mechanisms. Inflammation is the primary mechanism used by the body to restore normal structure and function to cells, organs and tissues, re-establishing homeostasis.

Minor physical challenges, such as working out, result in transient inflammation that triggers repair and growth of new muscles and stronger tendons. In this way, inflammation is a key mechanism that supports human health and survival.

The downside is that an abundance of inflammation can lead to disease.

Inflammation research has uncovered that the immune system maintains a complex and delicate balance mediated by interacting inflammatory molecules. In fact, the damaging health effects of eating junk food, being overweight and smoking are presented through inflammation.

When triggers of inflammation don't let up because of stress, obesity or diet, the immune system can spiral out of control. Persistent inflammation that serves no purpose can damage blood vessels and brain cells, trigger strokes and promote resistance to insulin. Heart disease, diabetes, stroke and cancer all have a common underlying theme—persistent inflammation.

Millions of Americans live with inflammation daily. Emerging evidence suggests that, like blood pressure, Americans should manage levels of inflammation to avoid health complications. Research has demonstrated that dietary supplement ingredients, such as omega-3 fats, boswellia (*Boswellia serrata*), turmeric (*Curcuma longa*), vitamin D and others, can act as modulators of excess inflammation.

However, products that act on inflammatory pathways present unique challenges for marketers because there is no bright line between normal healthy inflammation and chronic inflammation that is linked to diseases such as arthritis or inflammatory bowel disease (IBD).

Developing appropriate structure-function claims related to inflammation is a challenging task. For ingredients like omega-3 fats, there are hundreds of clinical trials in inflammatory diseases, such as rheumatoid arthritis, Crohn's disease and heart disease, but of course these claims are off-limits for dietary supplements. There is also research that shows omega-3 fats support healthy levels of inflammation after exercise or exposure to pollen, which is evidence that can be used to support claims such as "help maintain the body's normal inflammatory response."

Industry experts agree a gray area divides permissible and impermissible inflammation claims. I have been witness to industry consultants that suggest the term "inflammation" in any context is absolutely out-of-bounds because of its clear relationship to disease. However, this is contradictory to science. If a product or ingredient reduces transient post-exercise inflammation, it is at the core of what structure-function claims are intended to communicate to consumers.

Developing claims for dietary supplements can be tricky, but use of the term "inflammation" in structure-function claims in particular is a complex issue that impacts a wide swath of the industry. Responsible companies using the term should take a close look at their science, as well the context in which they make the claim. The Council for Responsible Nutrition (CRN) and VIRGO organized an [industry-wide webinar](#) to dive deeper into concepts surrounding inflammation and structure-function claims. Speakers

will include scientists, regulatory consultants, and a representative from FDA, all providing perspective and insight on ways to comply with regulations and stay on the right side of the law.

Providing consumers with truthful, non-misleading label claims and marketing messages without tripping into an illegal disease-claim pit is the goal. How do you turn structure-function claims from what critics call "a wink and a nod" into meaningful communication that fits on a bottle and doesn't land you in regulatory purgatory? Sign up for the May 7, 2013, webinar and hear from the experts.

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