



The Dietary Supplement Industry in the Time of Trump

Potential Opportunities and Pitfalls

by *Theodora McCormick*

The new administration came into office promising to loosen the regulatory environment for business and ease the burdens to sale, positioning, and marketing of consumer products. While this presents a great opportunity for the dietary supplement industry in the form of less regulation and less enforcement, there are also many potential pitfalls such as tainted products, blatant GMP violations,

and fraudulent marketing. Whether a so-called “regulatory holiday” is a golden ticket or impending disaster remains to be seen. Some of the possible risks and opportunities are outlined below, along with proactive steps industry members can and should take in order to take advantage of this new world order.



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History of FDA Regulation in Dietary Supplements Industry

The Federal Trade Commission (FTC) and Food and Drug Administration (FDA) are the two primary federal agencies that regulate the dietary supplement industry. FTC regulates dietary supplement advertising, while FDA regulates both finished dietary supplement products and dietary ingredients.

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA) manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from

marketing products that are adulterated or misbranded. Supplement companies are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.

FDA is responsible for taking action against any adulterated or misbranded dietary supplement after it reaches the market. There is no requirement that FDA review and approve supplement products and ingredients before a company can bring them to market. Thus, while federal law requires supplement makers to ensure that their products comply with all FDA regulations before they market them, the fact that they aren't approved by FDA before market is something that foes of the supplement industry have been critical of since DSHEA was enacted 23 years ago, and just one reason why industry self-regulation is so important.

Trump Administration Executive Orders

The current administration took office with the stated goal of reshaping the federal bureaucracy into a lean, businesslike operation. In the 10 months since he took office, President Trump has consistently sought to cut what he views as wasteful, duplicative, and unnecessary regulations that do not improve public safety. While most of the current administration's actions have conformed to standard conservative views emphasizing de-regulation and market-driven economies, President Trump's trade stance towards China is causing concern, if not outright panic, for some supplement manufacturers.

Big Changes Expected at FTC

Many believe that the most significant impact the new administration will have will be at FTC. The Obama administration was in power for two terms. As a result, FTC is undergoing a shift in leadership, and agenda, that it hasn't seen in almost a decade.

Under the Obama administration, FTC consistently sought to impose heightened, drug-style clinical trial standards on a variety of health benefit claims, including claims for dietary supplement products. FTC won some cases—particularly where disease claims were at issue, including much of the dispute with POM Wonderful, which included claims to treat or prevent serious diseases, such as prostate cancer and heart disease. However, FTC lost where it sought to impose those heightened standards on non-disease structure/function claims and the defendants offered credible expert testimony in support of their claims. FTC lost a dispute with Garden of Life where cognitive function claims for a children's omega product were at issue. FTC also lost a significant dispute with Bayer where it challenged claims that a probiotic would improve digestive health. In each of these cases, the court found that FTC sought to enforce a substantiation standard that went beyond its own guidance on the "competent and reliable scientific evidence" evidence standard. While FTC did win a few cases involving non-disease claims, they typically involved extremely aggressive claims and the defendant offered no expert testimony in support of them.

Most industry experts don't believe that the new administration will have the same appetite for trying to enforce stringent clinical standards in cases where companies have offered science

and qualified experts in support of their claims.

FDA's New Commissioner Is Friendly to the Supplement Industry

Dr. Scott Gottlieb, the new FDA Commissioner, served as an FDA Deputy Commissioner in President George W. Bush's administration. In response to a written question by Committee Chairman Orrin Hatch at his Senate Confirmation hearing in April, Dr. Gottlieb wrote that: "As someone who uses dietary supplements every day, I believe they serve an important role in health promotion for millions of Americans, and I support consumer access to these products." He also wrote that FDA's current regulatory framework under DSHEA provides adequate enforcement tools to remove unsafe dietary supplements from the market and "if confirmed, I would commit to enforcing DSHEA, as intended by Congress."

NDI Draft Guidance Still Lives, Maybe

A manufacturer of a dietary supplement that contains a new dietary ingredient (NDI) must submit a premarket notification called a new dietary ingredient notification (NDIN) to FDA at least 75 days before marketing a dietary supplement that contains an NDI. 21 U.S.C. 350b. However, dietary ingredients that were marketed in the United States before October 15, 1994, do not require premarket review by FDA. Currently, there is no authoritative FDA recognized list of pre-DSHEA "old dietary ingredients." On August 12, 2016, FDA issued a revised Draft Guidance that indicated it was willing to develop a list of dietary ingredients that were marketed before October 15, 1994.

Many industry experts believe that the proposed guidance would increase registration costs while exposing proprietary blends to competitor scrutiny. Some trade groups have argued that the 102-page document is burdensome, complex, and contrary to the law, and many expected the Trump administration to permanently shelve the draft NDI.

While the NDI draft guidelines have been in limbo since 2016 they are not dead yet. On October 3, 2017, FDA held a public meeting to discuss the future development of an authoritative list of “old” dietary ingredients. While it is unlikely that FDA will move quickly to compile a meaningful ingredient list, dietary supplement makers should nevertheless follow FDA’s progress and take advantage of the opportunity to provide input.

Barriers to Trade with China

Trade with China for consumer goods has always been a difficult act to balance. On the one hand, U.S. consumers have become addicted to low-cost goods. Corporations follow consumer demand, which means that they source and manufacture many products in China, which offers cheap labor and inexpensive raw materials. The United States offers low barriers to entry and a huge consumer base. In return, China has become the go-to raw ingredients supplier for the dietary supplement industry. It is estimated that China supplies the global dietary supplement industry upward of seventy percent of its raw materials and ingredients.

The barrier to entry in the United States has been extremely low. Companies that source ingredients from Chinese suppliers are worried that the Trump administration is going to levy tariffs on imported Chinese goods. This will increase the cost of finished products

which will hurt the industry. One possible solution that has been proposed is getting China to open up its market to companies that want to import finished products and lowering its barriers to trade. China has a consumer base the size of the entire U.S. population and these consumers have disposable income and an interest in the health benefits of supplements.

Industry Must Engage in Self-Regulation and Education

The stated goal of the Trump administration is to reduce burdensome and redundant regulations. While this is, on balance, very positive for the industry, public confidence depends greatly on FDA’s ability to ensure dietary supplements are safe. While the majority of supplement manufacturers are reasonable and careful there will always be some that are not. The industry has an important role to play and that role should be an active one. The dietary supplement industry has worked hard in recent years to clean up its image and change both the government and consumer perception of the industry through education and positive action.

The industry must continue to take an active role and engage in more self-regulatory initiatives. Among other things, this is an excellent time for industry to engage with FDA on some of its voluntary guidelines and best practices. In addition, the Council on Natural Nutrition has proposed implementing: (1) a program of continuing education, aimed not just at the public but at the medical profession and the government as well; (2) a “Seal of Quality Assurance” designed, developed, instituted, and administered within the industry and applied to existing and new products.

This designation would be available for products that have undergone testing created and overseen by industry experts and, where appropriate, in conjunction with FDA; (3) product labeling that clearly and accurately defines the contents of herbal and nutrient packages on the shelf; and (4) a concentrated, highly visible industry push to foster and encourage more doctors to embrace the concept of “integrated medicine.”

Millennials May Prove to Be an Even Bigger Market than Baby Boomers

As the buying power of baby boomers (the traditional consumers of supplements) weakens, the millennials are gaining industry attention. Millennials—who are already steeped in yoga, plant-based nutrition, meditation, and all manner of alternative wellness regimes—might prove to be an even bigger market than the baby boomers.

In conclusion, this is not business as usual. A so-called “regulatory holiday” offers both tremendous opportunity and tremendous risk. If consumers perceive that the law is not enforced, and that bad actors are participating in the market unimpeded, they will lose faith in the industry. Overly lax enforcement also feeds critics of the industry who say that DSHEA doesn’t work. Without cohesive federal oversight the industry may end up defending itself from adversaries who feel duty bound to act in its absence—including state attorneys general and class action lawyers.

Industry members should continue to contribute time, resources and effort to work with trade associations, lobby their representatives in Congress, and remain strategically open to change. **▲**