Overview
On February 11, 2019, the Food & Drug Administration (FDA) announced that it had sent a raft of warning letters to companies selling dietary supplements. The Federal Trade Commission (FTC) joined the FDA in issuing several of these warnings. The correspondence focused on advertisements and labels touting the supplements’ ability to treat or cure Alzheimer’s, cancer, and myriad other diseases. The warning letters specifically called out the manufacturers for making unapproved drug claims and deceptive statements. This crack-down reflects a comprehensive interagency effort to identify false and unsubstantiated health claims, and presages increased enforcement attention on the dietary supplements industry.

To this end, FDA Commissioner Scott Gottlieb, M.D., issued a statement outlining the agency’s strategic priorities on dietary supplements, and announcing new steps that will bring the agency’s dietary supplement program “into the twenty-first century.” This increased scrutiny may be good news for some consumers, as the Commissioner noted unapproved drug claims could cause some patients to forgo proven treatments. Nevertheless, the warning letters may spell trouble for companies who tout the health benefits of their supplements, and even conventional foods. Indeed, companies that make benign, well-substantiated, and non-misleading structure and function claims may find themselves in the crosshairs of the plaintiffs’ bar, who will likely use the FDA’s pronouncements on dietary supplements to test product advertisements and label claims in other segments of the food and beverage industry.

The FDA’s Concerns About the Current Regulatory Landscape
The FDA’s current regulatory scheme for dietary supplements dates back to 1994, when Congress passed the Dietary Supplement Health and Education Act (DSHEA). As the Commissioner noted, the dietary supplements industry has grown more than tenfold since then. Its annual sales now top $40 billion dollars, and comprise over 80,000 different products. He noted that three out of every four Americans now consume a dietary supplement. This rapid growth has repeatedly outpaced the FDA’s policies and its ability to manage emerging risks as new ingredients and products are developed, and the number of unproven or misleading claims made in marketing these products has flourished. The concerns expressed in the Commissioner’s February 11, 2019 announcement prompted the FDA to begin overhauling the way it oversees the industry, and features the establishment of the Dietary Supplement Working Group.
These concerns also led the FDA and FTC to issue the new warning letters described above. While some of the claims made by these companies appear so implausible as to make it unlikely that a reasonable consumer would take the supplements in lieu of proven medical treatment, the letters underscore that the FDA and FTC are serious about cracking down on unapproved drug claims and false/unsubstantiated advertising.

Next Steps in Revamping Regulatory Oversight of the Dietary Supplements Industry

In last week's statement, the FDA outlined three strategic priorities that will shape its approach to dietary supplements going forward. It is no surprise that its top priority is public safety. The second priority is to maintain product integrity and ensure the products contain the ingredients their labels say they do. The third is to support informed decision-making by consumers and healthcare providers.

The FDA also identified steps it plans to take to advance these objectives. One such step is the development of a rapid response tool that allows the agency to quickly alert the public about problematic ingredients and potentially dangerous products. Other steps include updates to premarket notification procedures for new dietary ingredients, the launch of a "Botanical Safety Consortium," and other collaborations with industry partners to evaluate ingredient mixtures and new toxicology tools. The Commissioner also proposed exploring possible amendments to the DSHEA, including a mandatory product listing requirement.

For present purposes, the most significant step involves the agency's decision to ramp up enforcement. In addition to issuing warning letters to supplement manufacturers and retailers, the agency intends to issue new guidance to the industry on products it considers adulterated and unlawful, warn consumers to avoid certain products containing undisclosed drug ingredients, and take steps internally to make it more efficient for pursuing enforcement actions. These efforts are all part of the agency's broader enforcement plan. The Commissioner pointed to several recent examples, including new guidance issued on dietary supplements containing pure or highly concentrated caffeine sold in bulk to consumers, and warnings issued to companies and the public regarding dietary supplements containing unsafe food additives, such as tianeptine, or undeclared drug ingredients, such as sildenafil or tadalafil, or that make misleading or unsubstantiated claims to treat certain health conditions, such as opioid addiction, erectile dysfunction, diabetes, pain and anxiety. The agency also plans to develop "new enforcement strategies," although it remains to be seen what those will entail.

The FDA indicated it will have more announcements in the coming months, and plans to hold a public meeting this spring. The meeting will address innovation and safety in the industry, and provide a forum for industry stakeholders to offer feedback on how the FDA should move forward in strengthening its dietary supplement program. Companies interested in voicing their concerns should plan to attend.

Follow-on Civil Litigation Risks

The FDA's new initiative will undoubtedly spur further interest in the dietary supplement industry by the plaintiffs' class action bar. An unwanted consequence of these initiatives may result in responsible manufacturers of supplements, conventional foods, and beverages receiving more demand letters and litigation. Class action lawyers have a habit of cherry-picking excerpts from warning letters directed to serious offenders, and using them to support putative class actions alleging that compliant health claims violate the law. It will be critical for companies facing such threats to look carefully at the context of the warning letters, and push back against claims where their labeling and advertising do not present a risk of deception, do not make drug claims, and have not caused consumers to suffer any economic harm.

[3] Id. at 2-3.
[4] Id. at 3.
[5] Id.
[6] Id. at 4. See also https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626349.htm
[8] Id. at 4.
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