

# FDA Tightening Oversight of Dietary Supplement Industry

John E. Villafranco, Donnelly L. McDowell

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This morning, the FDA [announced](#) its intention to engage in greater oversight of the dietary supplement industry. The announcement also conveyed that the Agency had sent 12 warning letters and five advisory letters to companies over the prior two weeks. Some of these letters were jointly issued by FDA and the Federal Trade Commission, focusing on what the two agencies consider to be illegal and deceptive claims in advertising and labeling for products intended to treat Alzheimer's and other serious diseases such as diabetes and cancer, rendering the products unapproved new "drugs" rather than "dietary supplements" under federal law.

In his statement, FDA Commissioner Scott Gottlieb stated an intent to step up FDA efforts to improve product safety and police deceptive claims. Amongst other initiatives, Mr. Gottlieb stated that the Agency is developing a new "rapid response tool" to alert the public if a supplement contains an illegal ingredient or poses a health risk. While supplement manufacturers should be pleased that efforts are being made to weed out bad actors, they should also be concerned about unintended consequences that might result from use of such a rapid response tool. The damage to a brand from an FDA alert could be significant.

Gottlieb also indicated that FDA is working to "develop [new] guidance for preparing [new dietary ingredient] NDI notifications" to help ensure that the regulatory framework is both sufficiently flexible and adequately protects public safety. As part of its work to modernize the NDI process, FDA is also planning to update its compliance policy regarding NDIs. Mr. Gottlieb also weighed in on the idea of creating an FDA registry, whereby supplement manufacturers would be required to list products and ingredients. The registry, presumably, would allow FDA to concentrate enforcement efforts, but before it could be created, Congress almost certainly would need to act. Gottlieb's statement seemed to acknowledge this, and he cited the possibility of "dietary supplement exclusivity" similar to the exclusivity presently enjoyed by drug manufacturers as another potential issue ripe for congressional consideration.

In order to concentrate on these issues and others affecting industry and consumers, Mr. Gottlieb reported that he has established a Dietary Supplement Working Group at the FDA, "comprised of representatives from multiple centers and offices across the agency." The Working Group will report directly to the Commissioner and will review "organizational structures, processes, procedures and practices in order to identify opportunities to modernize our oversight of dietary supplements." In addition to these steps, FDA will conduct a public meeting this spring that will focus on "responsible innovation and safety." All stakeholders are invited to provide comment on "how the FDA should strengthen the dietary supplement program for the future."

Much of the justification for increased oversight is centered on what FDA has characterized as a startling increase in the number of dietary supplements generally, and adulterated and misbranded

supplements specifically. Whether the framework that FDA will put in place is narrowly conceived to address this problem, without creating unnecessary and burdensome requirements on reputable companies, remains to be seen. Stakeholders should monitor these developments closely and consider engagement through public comments or participation at the public meeting given Gottlieb has made clear that the Agency wants to hear both from industry and consumers as it assesses how best to move forward.