FDA Announces Plan to Increase Oversight of Dietary Supplements

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The FDA's recent statement unveiling its goal to implement "one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years" (the "Statement")[1] emphasizes FDA Commissioner Scott Gottlieb's continued focus on enforcement against unlawful activities – including product promotions and advertising – that create substantial public health risk.

The existing framework under which the FDA regulates dietary supplements was shaped, in large part, by the Dietary Supplement Health and Education Act of 1994 (DSHEA).[2] While the growth and development of the dietary supplement industry has stimulated significant health advancements, it has also, according to the FDA, led to an increase in the number of adulterated and misbranded products on the market. These include "those [products] spiked with drug ingredients not declared on their labels, misleading claims, and other risks."[3]

On the same day that the Statement was published, the FDA sent 12 warning letters and five online advisory letters to 17 companies for allegedly making unproven claims that their products can prevent, treat, or cure Alzheimer's disease and other serious illnesses and conditions, including diabetes and cancer.[4] While these letters are the first of the FDA's enforcement efforts under the modernized regulatory scheme, they also reflect a continuation of its ongoing commitment to "protect consumers from Alzheimer's disease health fraud." Specifically, the Agency has issued more than 40 warning letters in the past five years against companies making Alzheimer's disease claims about more than 80 products, collectively.[5] The Statement reiterates that "[d]ietary supplements can, when substantiated, claim a number of potential benefits to consumer health, but they cannot claim to prevent, treat, or cure diseases like Alzheimer's."[6]

As the FDA continues to develop and implement a modernized framework for dietary supplement oversight, industry should expect to see continued, and likely increasing, enforcement against companies making serious medical claims about their products, particularly online and/or via social media platforms. In addition, the FDA's announced plans for the near future include steps to:

- Develop and implement a new rapid-response tool to quickly alert the public when supplements are found to pose a health risk or contain illegal ingredients
- Update the new dietary ingredient (NDI) compliance policy, and amend/issue guidance on the NDI notification process to ensure that it effectively allows the FDA to thoroughly evaluate the safety of NDIs before they are made available to consumers
- Develop new strategies and continue efforts to improve existing internal processes for taking efficient enforcement action when products claiming to be supplements contain unlawful

ingredients[7]

- Consider and solicit industry commentary as to whether DSHEA should be amended in accordance with the updated framework (e.g., to establish avenues for dietary supplement exclusivity and/or add a mandatory product listing requirement)

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[1] See FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight*, U.S. Food and Drug Administration (Feb. 11, 2019).

[2] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

[3] *FDA Statement, supra*, note 1.

[4] *See id.*; FDA News Release, *FDA takes action against 17 companies for illegally selling products claiming to treat Alzheimer's disease*, U.S. Food and Drug Administration (Feb. 11, 2019) [hereinafter *FDA News Release*].

[5] *FDA News Release, supra*, note 5.

[6] *FDA Statement, supra*, note 1.

[7] For example, the FDA issued guidance in April 2018 to clarify that dietary supplements containing pure or highly concentrated caffeine in powder or liquid forms are considered unlawful when sold in bulk quantities directly to consumers. Due to the significant public health threat, the guidance took immediate effect. *See* FDA News Release, *FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine*, U.S. Food and Drug Administration (April 13, 2018).