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MEMORANDUM

From: Martin J. Hahn
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Re: **FDA Announces Plans for Modernizing and Reforming Dietary Supplement Oversight and Issues Batch of Warning Letters Over Unlawful Alzheimer's Claims**

The Food and Drug Administration (FDA) recently announced a plan for "policy advancements with the goal of implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years."1/ FDA Commissioner Scott Gottlieb reflected on the 25th anniversary of the Dietary Supplement Health and Education Act, and stated his commitment to ensuring FDA achieves the right balance between consumer access to lawful supplements, while upholding the agency's public health obligation to protect consumers from unsafe and unlawful products, and holding unlawful actors accountable. The announcement sets lofty goals and teasers for details that are forthcoming. FDA also articulates several priorities for modernizing and reforming its oversight of dietary supplements, as discussed further below. As a part of these efforts, the agency issued over a dozen Warning Letters to companies marketing products as dietary supplements but that were labeled with unapproved disease claims, such as claims about the prevention of Alzheimer's disease.

In modernizing the agency's approach to regulating dietary supplements, Commissioner Gottlieb articulated the following priorities:

1. Communicate to the public as soon as possible when there is a concern about a dietary supplement on the market.
2. Ensure FDA's regulatory framework is flexible enough to adequately evaluate product safety while also promoting innovation.
3. Continue to work closely with industry partners, and engage in a public dialogue to get valuable feedback from dietary supplement stakeholders.
4. Develop new enforcement strategies.

As a part of these comprehensive efforts, FDA issued 12 Warning Letters and five online advisory letters to companies whose products, many of which were positioned as dietary supplements, but

1/ *See* 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, Feb. 11, 2019, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm.

were illegally marketed as unapproved new drugs because the products bear unproven claims to prevent, treat, or cure Alzheimer's disease, in addition to other serious diseases and health conditions, such as diabetes and cancer. 2/ FDA explains that in addition to the claims not being substantiated or appropriate for dietary supplements, such claims can discourage patients from seeking medical treatment. The Warning Letter initiative is just one part of FDA's overall efforts to update the agency's framework governing dietary supplements. Commissioner Gottlieb notes that the agency has taken many similar actions in the past year, including Warning Letters to companies marketing dietary supplements containing concentrated caffeine, male enhancement drugs, and tianeptine, a compound used in products with unproven claims about treatment of opioid addiction. Further, Commissioner Gottlieb explains that FDA has also been engaged in active compliance and enforcement efforts against companies that have shown a persistent inability to comply with current good manufacturing requirements (GMPs) and to protect the public from unsafe imports and recalled products.

In addition to these enforcement actions, FDA announced the following developments to modernize FDA's oversight of dietary supplements:

- Dietary Supplement Working Group Priorities. FDA established a Dietary Supplement Working Group, which created the following strategic priorities for dietary supplements to ensure FDA is focusing attention and using resources in ways that make sense.

    1. Ensuring product safety.
    2. Maintaining product integrity: ensuring products contain what they say they contain and nothing else, and are consistently manufactured according to quality standards.
    3. Informed decision-making: foster environment where consumers and health care professionals are able to make informed decisions about recommending, purchasing, using, supplements.
        - FDA will announce more in coming months about what steps the agency is taking to advance these priorities.

- Rapid Response Tool. Developing a new rapid response tool to alert the public so consumers can avoid buying or using products with that ingredient, and to notify responsible industry participants to avoid making or selling them.

- Submission of New Dietary Ingredient Notifications. Taking steps to foster submission of new dietary ingredient notifications (NDINs). In addition to developing guidance on NDINs and update its compliance policy, FDA intends to hold a public meeting in the spring on responsible innovation in the dietary supplement industry, which will provide stakeholders an opportunity to provide FDA with feedback on how to modernize NDIN submissions.

- Dietary Supplement Exclusivity and Other Barriers to Innovation. FDA indicated it intends to address other challenges that could act as barriers to dietary supplement innovation and safety. In particular, the agency is assessing what the right incentives might be for establishing dietary supplement exclusivity, and the scope of permitted dietary ingredients.

2/ *See* FDA takes action against 17 companies for illegally selling products claiming to treat Alzheimer's disease, Feb. 11, 2019, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631064.htm.

- In addition to exploring potential exclusivity for dietary supplements, Commissioner Gottlieb also noted a mandatory product listing requirement could provide significant benefits by improving transparency in the market and promoting risk-based regulation, as well as helping to facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors.

- FDA created the Botanical Safety Consortium, a public-private partnership to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. This group will look at novel ways to use cutting-edge toxicology tools, including alternatives to animal testing, to promote the goals of safety and effectiveness we share with consumers and other stakeholders.

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We will continue to monitor FDA's efforts to modernize and reform the regulation of dietary supplements. Please contact us if you have any questions on this or any other matter.