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FDA Announces New Efforts to Strengthen Regulation of Dietary Supplements

February 12, 2019

FDA Commissioner Scott Gottlieb issued a statement on February 11 announcing new efforts to strengthen regulation of the dietary supplement industry by modernizing and reforming FDA's oversight. The statement highlights specific policy advancements and priorities aimed at "implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years."

Key steps include the development of a "new rapid-response tool" to alert the public and industry participants as soon as possible when there is a concern about a dietary supplement product or its ingredients. Another priority is to ensure FDA's regulatory framework is flexible enough to adequately evaluate product safety while also promoting innovation, with the key goal of fostering the submission of new dietary ingredient (NDI) notifications and updating the agency's policy regarding NDI compliance. Additionally, Commissioner Gottlieb indicated FDA is interested in public input as to whether additional steps to modernize the Dietary Supplement Health and Education Act of 1994 (DSHEA) are necessary, including potentially exploring issues such as dietary supplement exclusivity, a mandatory product listing requirement, and the scope of permitted dietary ingredients.

Other agency priorities include continuing and renewed efforts to work closely with FDA's industry partners; the establishment of a Dietary Supplement Working Group within the agency, which will be tasked with "taking a close look at [FDA's] organizational structures, processes, procedures and practices in order to identify opportunities to modernize [FDA's] oversight of dietary supplements"; and continued enforcement actions to protect public health and safety while developing new enforcement strategies. On the topic of enforcement, FDA concurrently announced with Commissioner Gottlieb's statement that the agency is taking action against 17 companies for illegally selling products claiming to treat Alzheimer's disease, as well as a number of other serious diseases and health conditions, through issuance of 12 warning letters and five online advisory letters.

Finally, Commissioner Gottlieb announced FDA plans to provide additional details in the coming months on the steps the agency is taking to continue moving its dietary supplement program forward to implement the agency's priorities. In that regard, FDA plans to hold a public meeting in spring of 2019 on the topic of responsible innovation in the dietary supplement industry. All industry stakeholders are invited to participate.

Commissioner Gottlieb's full statement is available here.

For more information about how this issue may affect your business or related matters, please contact the author of this alert, Kyle Diamantas, or any member of Baker Donelson's FDA Group.