LEGAL UPDATES

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FDA Takes Steps to Modernize Regulation of Dietary Supplements

Industry

Food Systems

For the first time in 25 years, the Food and Drug Administration (FDA) announced a plan to modernize dietary supplement regulation and oversight. The announcement sets lofty goals and articulates the following priorities:

Communicate to the public as soon as possible when there is a safety concern about a dietary supplement on the market.

Ensure FDA's regulatory framework is flexible enough to adequately evaluate product safety while also promoting innovation.

Continue to work closely with industry partners, and engage in a public dialogue to get valuable feedback from dietary supplement stakeholders.

Develop new enforcement strategies.

On the same day as the announcement, the agency issued over a dozen warning letters and advisory letters to companies marketing products as dietary supplements but that FDA considered to be intended for unapproved disease indications, such as claims about the prevention of Alzheimer's disease. Following the regulatory letters issued the day of the announcement, FDA has issued an additional 11 warning letters to companies marketing products with 1,5-Dimethylhexylamine (DMHA) and phenibut, because FDA asserts that the products at issue are being unlawfully marketed as dietary supplements. The agency also has taken many similar actions in recent years, including sending warning letters to companies marketing supplements containing concentrated caffeine, male enhancement drugs, and tianeptine, as well as for violations of the current good manufacturing practice (cGMP) regulation for dietary supplements.

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In addition to these enforcement actions, FDA has formed a Dietary Supplement Working Group to create strategic priorities for dietary supplements and ensure FDA is correctly focusing its efforts and resources. FDA also announced that the agency is creating a Botanical Safety Consortium to promote scientific innovation in evaluating the safety of botanical ingredients and mixtures, modernizing the process for submitting new dietary ingredient notifications (NDINs), and addressing other barriers to innovation, such as establishing a scheme for supplement exclusivity.

First Steps towards Modernization

FDA is hosting a public meeting on Thursday, May 16, 2016, in College Park, MD, as a first step to implementing this plan. The meeting will allow stakeholders an opportunity to present ideas to the agency on these proposed plans. FDA has identified the following topics to be discussed during the meeting:

The scope of the phrase "dietary substance for use by man to supplement the diet by increasing the total dietary intake" as used in the Dietary Supplement Health and Education Act of 1994 (DSHEA), which determines, in part, whether a product meets the definition of a dietary supplement.

Understanding the exceptions to the premarket notification requirements for dietary supplements, and whether and how growth in the dietary supplement marketplace since 1994 has altered the impact of DSHEA.

Ways to incentivize responsible innovation through potential commercial or market advantages.

Use of enforcement to promote overall compliance with the premarket notification requirement.

Individuals interested in attending the public meeting in person and testifying may register with FDA by May 6. The meeting will also be streamed via webcast, but FDA suggests individuals attending online preregister as well.

Rapid Response Tool

FDA also recently unveiled a new Dietary Supplement Ingredient Advisory List. This is a rapid response tool that is meant to alert the public and supplement industry when FDA identifies ingredients that do not appear to be lawfully marketed in dietary supplements, but does not necessarily indicate that the ingredient is unsafe. The list is generated based upon a preliminary assessment by FDA that the ingredient appears to be excluded from use in dietary supplements, does not appear to be a dietary ingredient and is not an approved food additive or generally recognized as safe (GRAS) for use, or was not subject to the required pre-market notification.

What This Means to You

This is the first time FDA has considered adjusting its approach to the regulation of dietary

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supplements since DSHEA was first enacted. The public meeting and FDA's modernization efforts on a broader level present an opportunity for both trade groups and individual companies to understand and influence how FDA will alter the process by which dietary supplements are introduced to the market and how FDA will evaluate their safety. Given FDA's focus on innovation, it will be especially important for companies developing novel dietary supplements or new dietary ingredients to understand how these potential changes may affect the regulatory process for new products.

Contact Us

Husch Blackwell has experience working with manufacturers and trade groups on important FDA rulemaking. Further, our FDA team regularly advises dietary supplement manufacturers on the regulation of new dietary ingredients and products, and has members with the required scientific backgrounds to help strategize and organize responses. Our FDA regulatory lawyers are available to discuss the announcement, upcoming meeting, and how companies can appropriately prepare. Contact Seth Mailhot, Emily Lyons or your Husch Blackwell attorney.

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