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ALERT

FDA Considers Modernizing Dietary Supplements' Regulatory Pathway

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The U.S. Food and Drug Administration's (FDA) Office of Dietary Supplement Programs (ODSP) recently held a public meeting to solicit input from stakeholders on how the Agency should regulate modern dietary ingredient innovations. The March 27 meeting on "Exploring the Scope of Dietary Supplement Ingredients" primarily focused on the definition of "dietary substance" under the Dietary Supplement Health and Education Act of 1994 (DSHEA). In holding this meeting, FDA sought to clarify the regulatory pathway that applies to new dietary ingredients (NDIs) and novel technologies used to produce existing dietary ingredients. The key takeaway for stakeholders is that FDA has signaled a willingness to revisit its historically strict interpretation of DSHEA terminology. This could pave the way for Agency recognition of substances not previously present in conventional foods or developed using novel technologies to be deemed permissible dietary ingredients in supplement products.

Background

In 1994, DSHEA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to define "dietary supplement" and create a regulatory framework for these products. In addition to specifically listing vitamins, minerals, botanicals, and amino acids as the type of substances that can qualify as a dietary ingredient, the statutory definition also includes "a dietary substance for use by man to supplement the diet by increasing the total dietary intake" (Clause E of Section 201(ff)(1)). Importantly, DSHEA excluded ingredients used in dietary supplements from the definition of "food additive." Nonetheless, for the purpose of NDIs, FDA interprets "dietary substance" to be limited to food or food components that humans consume as part of their usual diet. This narrow statutory

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interpretation has raised concern within the regulated industry for many years, given that it presents significant obstacles to product innovation and the introduction of new production technologies in the dietary supplement space.

This meeting is not the first time FDA has requested input from stakeholders on modernizing regulatory oversight of dietary supplements. FDA held a public meeting in 2019 raising similar questions on the scope of Clause E and how to manage innovation in the industry while ensuring that the safety of supplements is properly evaluated. Despite the Agency's historical approach to NDIs, FDA's willingness to reopen the discussion in 2026 signals that the Agency may be poised to reconsider its long-standing interpretation of the term "dietary substance" under DSHEA.

Public Meeting

At the meeting, FDA requested input from stakeholders on whether Clause E should encompass substances that have not historically been part of the human diet. Industry stakeholders advocated for a broad reading of Clause E and emphasized that Congress intentionally used expansive language in DSHEA in order for this clause to act as a "catch-all" provision. They noted that this interpretation is supported in the legislative history, which includes, among other things, a list of the types of substances that could be included in dietary supplements, a number of which had not been in the human diet prior to introduction as dietary ingredients. These stakeholders also stated that requiring NDIs to first be in conventional foods is contrary to Congress' intentional creation of the dietary supplement pathway, which excludes such ingredients from the definition of a food additive. By contrast, consumer advocates asserted that expanding the definition of "dietary substances" to include substances not commonly consumed in foods would undermine consumer safety and exceed congressional intent by making the word "dietary" meaningless. While FDA did not put forth a particular interpretation during the public meeting, the FDA Deputy Commissioner for Human Foods, Kyle Diamantas, stressed the importance of modernizing regulatory oversight of dietary supplements and the need to "cut red tape." However, the Director of ODSP, Dr. Cara Welch, cautioned that any new working definition for "dietary substance" must be anchored in the text of DSHEA.

Another notable theme was FDA's interest in how new production technologies, such as synthesis, cell culture, precision fermentation, and recombinant production, fit within the existing regulatory framework, and how FDA can properly assess the ingredients produced by these technologies. FDA additionally invited stakeholder input on the scientific criteria to be considered when determining the identity of a substance, particularly for substances that are commonly found in dietary supplements but not explicitly listed in DSHEA's definition, such as peptides, proteins, enzymes, and microbials. These discussions signal potential future efforts to develop more transparent identity standards, which could reduce uncertainty surrounding the types of changes to an existing dietary ingredient that could change its status to an NDI that requires an NDI notification (NDIN).

While FDA did not commit to a particular interpretation of DSHEA at the public meeting, the discussion provides insight into the Agency's current thinking. Specifically, this meeting signals FDA's willingness to revisit its long-standing interpretation of DSHEA terms and how the Agency plans to regulate modern dietary ingredient development and emerging production technologies. The opportunity to submit written comments

to FDA concluded on April 27, 2026. At the 2026 Food and Drug Law Institute Annual Conference on May 6, Dr. Welch mentioned that FDA is currently reviewing the nearly 1,000 comments the Agency received in response. She additionally noted that FDA is working to finalize guidance on the NDIN submission process and is also considering proposing separate guidance to clarify the meaning of "dietary substance."

Wiley's Food & Drug Practice will continue to monitor developments as FDA refines its approach to regulating the dietary supplement industry. For more information, please contact one of the authors of this alert.