Council for Responsible Nutrition
1828 L Street, NW, Suite 220 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

May 27, 2025

CRN Comment: FTC Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers

The Council for Responsible Nutrition (CRN) is providing this comment in response to the Federal Trade Commission's (FTC) "Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers" issued on April 13, 2025, in response to President Trump's Executive Order on Reducing Anti-Competitive Regulatory Barriers.

CRN is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers.[1] This comment concerns regulatory issues related to the Food, Drug, and Cosmetic Act (FDCA) and Food and Drug Administration (FDA) actions that impact dietary supplement competition, innovation and restrict consumer access to safe and beneficial nutrition products that support public health.

Specifically, we are writing regarding FDA practices concerning the application of section 201(ff)(3)(B) of the FDCA (referred to as "drug preclusion" throughout this comment) that appear to favor drug interests over those of dietary supplements in a manner that restricts nutrition and health innovation.[2] CRN's concerns have been expressed to FDA in several citizen petitions, including a petition that has been pending with the agency for over two years.[3] While FDA has indicated that it will respond to that petition by the end of July 2025, CRN believes it is important to raise its concerns with the FTC in response to the FTC's recent request for comment over anti-competitive regulatory barriers and prior to the FDA's represented response date.

FDCA Section 201(ff)(3)(B) Background and FDA Application Creating Anti-Competitive Effects

A. FDCA Section 201(ff)(3)(B) ("Drug Preclusion" Clause)

The Dietary Supplement Health and Education Act (DSHEA), which amended the FDCA in 1994, created dietary supplements as a newly defined product category regulated by FDA to preserve consumer access to these products as important tools that support public health and nutrition. DSHEA included language

[1] CRN member companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 180 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers.

[2] 21 U.S.C. § 321(ff)(3)(B).

[3] *See e.g.,* Citizen Petition Requesting FDA Reconsider Its Position with Respect to the Application of Section 201(ff)(3)(B) of the Food, Drug, and Cosmetic Act; Acknowledge That Agency Prior Statements and Actions Cannot be Reversed on Drug Preclusion Grounds; and Clarify Its Position on Rulemaking (May 9, 2023); CRN Citizen Petition Requesting FDA Allow N-acetyl-L-cysteine (NAC) to be Marketed as a Dietary Supplement (June 1, 2021) ("CRN NAC Citizen Petition"); Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Hemp-Derived Cannabidiol (CBD) (June 16, 2020).

defining the type of ingredients that can be included in dietary supplements. As part of this definition, Congress included exclusion language removing certain dietary supplement ingredients, that otherwise would be lawful dietary ingredients, from consideration where that ingredient was the same ingredient as a drug ingredient and the drug use of the ingredient was "first-to-the-market." This language (*i.e.*, "drug preclusion") was intended to provide limited protection for "bona fide new drug ingredients as well as research investment into natural ingredients for use as new drugs."[4]

An ingredient was only to be removed from use in a dietary supplement if certain narrow criteria were met, such as that the drug and dietary supplement ingredient were the same "article"[5] and either (1) the ingredient was approved by FDA for drug use before being marketed as a dietary supplement ingredient; or (2) where a drug company had filed for an investigational new drug application for the ingredient, engaged in substantial clinical investigations necessary for drug approval, and made these investigations public, ensuring that a dietary supplement company could determine an ingredient's precluded status before investing their own resources in bringing that ingredient to market. These provisions were intended to ensure that preclusion would only protect drug interests under unique narrow circumstances where the introduction of a dietary supplement ingredient into the market after that ingredient was approved as a drug or substantially investigated as a drug, would deter a drug company from investing in the drug approval process. If an ingredient is marketed in a dietary supplement before it is used in a drug, no monopoly is given for the drug purpose, and the ingredient is permitted to co-exist in both drugs and dietary supplements in compliance with the unique regulatory regimes for these products.[6]

B. FDA's Recent Anti-Competitive Application of Drug Preclusion

Despite Congress's intent that drug preclusion only apply to a narrow set of circumstances, in practice, FDA has used drug preclusion to block ingredients from being accessible as supplements in a number of broad circumstances that appear to be contrary to the Congressional purpose of this clause. These include situations where the ingredient used in drug products was vastly different in form and dose from that used in supplements; the ingredient had only been subject to limited study by drug companies (and in at least one circumstance had been publicly abandoned for drug use); FDA acted to retroactively remove an ingredient from the market that had co-existed as a dietary supplement with drug products for decades before the drug preclusion clause was enacted; and numerous other circumstances that over the last three decades have created a system that overly advantages drugs at the expense of dietary supplements.

---

[4] I. Scott Bass & Anthony L. Young, *The Dietary Supplement Health and Education Act: A Legislative History and Analysis* (1996) at 36.

[5] The term "article" is not defined in section 201(ff)(3)(B) but presumably refers to an ingredient in a substantially similar form, dose, and with other characteristics as to pose a deterrent threat for drug research and investment. The term "article" is used elsewhere in the FDCA to describe drug products and drug ingredients, however, the scope of the term changes depending where in the FDCA the term appears. The only court to analyze the meaning of the term "article" accepted a broad definition in favor of drug interests, giving deference to FDA's interpretation under the now overturned Chevron doctrine. *Pharmanex v. Shalala,* 221 F. 3d 1151 (10th Cir. 2000).

[6] By way of example, EPA found in omega-3 fatty acids, often derived from fish oil, are common dietary supplement ingredients; however, certain forms of EPA have also been approved for drug use. Not only could the form and dose of an ingredient be different in a dietary supplement for safety and other legal reasons, but dietary supplement marketing requirements are distinct from drug marketing requirements, with dietary supplements limited in the types of claims that can be made for a product.

Essentially, what was intended by Congress for infrequent, limited use has been increasingly cited by FDA to stifle innovation and block consumer access to numerous safe and beneficial dietary supplement ingredients.

- For example, just recently, FDA blocked an ingredient's use in dietary supplements after FDA had reviewed numerous legally required dietary supplement safety and claim notifications for that ingredient for years without raising any concerns that the ingredient was drug precluded.[7] After years of never raising an objection, however, FDA reversed its determination related to the ingredient's legality as a dietary ingredient "[b]ased on new information that came to light when [the agency was] reviewing another notification."[8] This new information was a statement by a drug company, alleging that an ingredient being studied by that company was the same "article" as the dietary supplement ingredient.[9] Despite the fact that the drug company's statement appeared to be the first time it made its drug investigations public and that the drug investigations appeared to be in a preliminary phase that did not reach the threshold necessary to trigger drug preclusion, FDA took the position that the existence of a non-public investigational new drug application filed with FDA and the preliminary studies cited by the drug company were enough to preclude the ingredient's supplement use.[10]

- The above reversal was similar to FDA's actions regarding two other dietary ingredients where FDA reviewed safety and claims notifications for decades without objection before calling into question the status of the ingredients under drug preclusion.[11] Each of these cases creates compelling inequities by signaling to a company that the article is a legitimate dietary ingredient, only to reverse course after business decisions have been made in reliance on FDA's statements. One of these ingredients had co-existed as a nutritional supplement and a drug ingredient prior to the enactment of the drug preclusion clause, negating any concern that the dietary supplement use could deter drug company research and investment. That ingredient was also approved as a drug

---

[7] *See* Letter from FDA CFSAN to SyncoZymes Co., Ltd., Regarding NDIN 1247 (May 16, 2022); Letter from FDA CFSAN to Willy Chemicals, Inc., Regarding NDIN 1174 (Nov. 2, 2020); Letter from FDA CFSAN to Willy Chemicals, Inc. Regarding NDIN 1189 (Feb. 11, 2021); Letter from FDA CFSAN to Willy Nutra, Inc. Regarding NDIN 1234 (Jan. 18, 2022).

[8] Letter from FDA CFSAN to SyncoZymes Co., Ltd Regarding NDIN 1240 and 1247 (Nov. 4, 2022).

[9] Letter from Metro International Biotech, LLC to FDA (Dec. 1, 2021).

[10] The actions of the agency are particularly egregious here where FDA permitted companies to move forward with investments in safety research, completing a regulatory required safety review and notification process, and committing funding to marketing and advertising, without objecting to the ingredient's use under drug preclusion. When FDA staff responsible for review at the Center for Food Safety and Applied Nutrition (CFSAN) acknowledged the May 2022 supplement notification with no objection, it appears that FDA staff was not even aware of the purported investigational new drug application for the ingredient, demonstrating the danger and unfairness of using non-public data to trigger drug preclusion protection—if FDA staff are not even able to discern whether drug preclusion protection attaches to an ingredient, how could dietary supplement companies make this determination and make informed decisions about the commercial success of such new ingredients?

[11] *See* CRN NAC Citizen Petition (June 2021); FDA Request for Comment on the Status of Vinpocetine (Sept. 7, 2016).

in a substantially different form than its use in dietary supplements (inhalable for drugs versus orally ingested for dietary supplements) further nullifying any deterrent effects.[12]

- In other situations, FDA blocked the use of a botanical ingredient in dietary supplements despite clear differences between the proposed supplement and drug uses. Notably, when the ingredient was used in a drug it was isolated from other plant constituents and used in extremely high doses compared to the low dose amounts that were the subject of two FDA dietary supplement safety notifications. Isolating a plant constituent from other components of the plant that the component is extracted from effects the behavior of a substance, which should change FDA's analysis regarding whether the ingredient is similar enough to be the same "article" as a drug ingredient and subject to drug preclusion.[13]

- In another concerning situation, a company investigated an ingredient for drug use but determined that it had better application as a nutrient for use in dietary supplements. Concerned that the company's own research could block supplement use, the company submitted a citizen petition requesting that FDA declare the ingredient appropriate for use in dietary supplements despite the earlier drug trials.[14] FDA, however, declined to substantively answer the questions raised in the petition, citing a lack of agency resources. In this instance, a company's own scientific research to determine how an ingredient might be beneficial for human health blocked the ingredient's use in the most beneficial manner. Such actions have the effect of stifling both drug and nutrition research innovation out of concerns that moving down the drug regulatory path too early could harm future health applications of the ingredient.

CRN also has pointed out repeatedly that, despite a determination that an ingredient is precluded, Congress gave FDA the discretionary, statutory authority to promulgate regulations allowing consumer access to the ingredient as a dietary supplement.[15] FDA still has never used this authority.[16] CRN believes that if FDA insists on taking such an expansive view of the express statutory language, then it must immediately begin to use the discretion also afforded by the statute to create a pathway for granting exceptions when the equities involved demand it.

---

[12] *See* CRN NAC Citizen Petition.

[1313] *See* further details in article published in Regulatory Focus *– Drug Preclusion and public health: The case for a narrow interpretation of 'article'*, M. Olsen & D. Garza (Nov. 17, 2022).

[14] Citizen Petition from ViGuard Health, Docket No. FDA 2017-P-6245 (Oct. 23, 2017).

[15] FDCA § 201(ff)(3)(B) (providing that a drug precluded ingredient would be lawful in a dietary supplement if "the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter").

[16] FDA, Policy Regarding N-acetyl-L-cysteine: Guidance for Industry (August 2022) (stating that "FDA intends to exercise enforcement discretion until either of the following occurs: we complete notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement . . . or we deny the NPA citizen petition's request for rulemaking"). This same guidance indicates that FDA would move forward with rulemaking unless the agency identified any safety-related concerns for NAC. NAC has been sold safely for decades as a dietary supplement, with no safety issues raised by FDA. Further, companies provided FDA with NAC safety data, at FDA's request, in January 2022. Almost three years later, FDA has neither identified any safety-related concerns, nor moved forward with rulemaking.

CRN Request for FTC Action

Contrary to Congress's stated purpose for the drug preclusion clause, FDA has increasingly interpreted section 201(ff)(3)(B) over nearly three decades in a manner that overly advantages drugs at the expense of dietary supplements. The continued reading of the drug preclusion provision in deference to drug company interests runs contrary to the statute's text, structure, history, and purpose. CRN has raised several concerns that the agency's interpretations are inconsistent and favor providing the broadest protections to drug interests. FDA's only consistent interpretation of drug preclusion has been to adopt the broadest possible reading to further the interest of drug companies at any cost—to the detriment of supplement companies and consumers.

CRN requests that FTC review the FDA's anti-competitive actions as it relates to section 201(ff)(3)(B) drug preclusion and take steps within its authority to help ensure that both the FDA's promised response to CRN's May 2023 citizen petition and agency action moving forward ensure a balanced approach between supplement competition, innovation, and access, and drug research and development interests, as Congress intended.

We appreciate the Commission's consideration of our comment and welcome any questions.

Sincerely,

Megan Olsen
Senior Vice President & General Counsel