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September 15, 2025

Docket Clerk
Office of Legal Policy
U.S Department of Justice
950 Pennsylvania Ave. NW
Washington, DC 20530

Re: Docket No. OLP182 – Request for Information on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce

To Whom it May Concern:

The Council for Responsible Nutrition (CRN) is providing this comment in response to the August 15, 2025 Department of Justice (DOJ) request for information regarding state laws significantly and adversely affecting the national economy or interstate commerce. CRN is the leading trade association representing the dietary supplement industry, including its manufacturers and suppliers.[1] CRN members provide products that are critical to helping Americans maintain their health and ensure that consumers have access to important vitamins and nutrients that they may not be able to receive from their diet alone.

Since 1973, CRN has advanced its mission of fostering a climate for responsible companies to improve consumers' health and nutrition through the availability of safe, legal, and responsibly developed, sourced, manufactured, and marketed science-based dietary supplements, functional foods, and their ingredients. Dietary supplements are extensively regulated by the federal government through the Food and Drug Administration (FDA) and other federal agencies.

I. New York Law of Concern: Background

In response to the DOJ request for information, CRN is raising concerns with a recently enacted state law in New York that restricts access to important nutritional products and attempts to unlawfully restrict legal speech about the health benefits of these products. Specifically, New York General Business Law § 391-oo restricts access to dietary supplement products that are "labeled, marketed, or otherwise

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the 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 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

represented for the purpose of achieving weight loss or muscle building . . . ."[2] The law bans the sale of these dietary supplements to consumers under the age of 18, as well as those over the age of 18 who lack sufficient government identification.

Under the guise of purportedly addressing eating disorders in minors, in 2023, the New York state legislature enacted a haphazardly drafted, vague, overbroad law that limits the sale of dietary supplement products where any statement or representation suggests that a product (or one of its ingredients) may assist in weight loss, muscle building, muscle maintenance, the process by which nutrients are metabolized by the human body; or where other ambiguous statements and factors purportedly position a dietary supplement as a product that can be used for the "purpose of achieving weight loss or muscle building." While CRN applauds New York's efforts to address significant mental health issues, there is absolutely no evidence demonstrating a causal link between dietary supplements and eating disorders – and there is certainly no evidence that federally regulated, legal dietary supplements are unsafe for minors based solely on their label claims or how they are marketed or otherwise represented.[3]

The law affects not only how dietary supplements are sold in New York but has unintended consequences on how supplements are sold nationwide, harming both New York consumers and those located throughout the country. The law makes dietary supplements less accessible and more expensive for everyone, as the uncertainties surrounding which products are restricted will chill speech designed to assist consumers in making educated decisions concerning their health, stifle product innovation, increase transaction costs, and could push dietary supplement manufacturers out of the market entirely. And of course, in New York, the law deprives minors of dietary supplements that may be beneficial for their health. CRN members also anticipate lost revenue from market conditions, lost sales from minors and lawful consumers, and impairments to their existing business relationships, including with retailers, distributors, and other third parties.[4]

The New York Governor, Kathy Hochul, recognized the burdens of similar legislation when she vetoed a prior iteration[5] of the law in 2022, finding that New York state agencies do "not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA" and "[i]t would [] be unfair to expect retailers to determine which products they can and cannot sell over the counter to minors, particularly while facing the threat of civil penalties."[6] That version of the law would have prohibited the sale of products to minors "based on a list of ingredients" that would have been created by the New York Department of Health.

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[2] Defining one class of covered products as "[d]ietary supplements for weight loss or muscle building", which means "a class of dietary supplement [as that term is defined in the Food, Drug, and Cosmetic Act (FDCA)] that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building, but shall not include protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food marketed as containing protein contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building." NY GBL § 391-oo(a).
[3] *See* Susan J. Hewlings, Eating Disorders and Dietary Supplements: A review of the Science, NUTRIENTS 15(9):2076 (2023), *available at*, https://www.mdpi.com/2072-6643/15/9/2076.
[4] Declaration of Steven M. Mister, *Council for Responsible Nutrition v. James*, No. 24-cv-01881 (S.D.N.Y. Apr. 3, 2024).
[5] *See* New York Assembly Bill Number 431-C (2022).
[6] *See* Hochul, Veto #122, December 23, 2022.

Despite the Governor's recognition that a law restricting how federally regulated dietary supplements are sold in New York would be "unfair" to businesses and should be left to the rightful jurisdiction of the FDA, the state legislature continued to target these products. In 2023, the state legislature passed a new iteration of the age-restriction legislation that targeted products based on truthful and legal speech. This legislation, perplexingly given her earlier objections, was signed into law by the Governor, and enacted as NY GBL § 391-oo.

The New York law was opposed by CRN and other dietary supplement trade associations, retailers, and a myriad of other businesses affected by this nonsensical law. One retailer association, for example, noted in their Memorandum of Opposition that the law would force retailers to request ID in order to sell "***legal*** dietary supplement products" and would cause adult consumers to change their behavior regarding how they access these products.[7] This organization succinctly pointed out what the New York state legislature and Governor refused to acknowledge in passing this misguided legislation – "[a]ny products that have been shown to cause negative health effects are already illegal to sell to minors or adults. The additional restrictions are unwarranted."[8]

For these and a number of other reasons, CRN filed suit in New York in 2024 before the law went into effect, seeking a declaration that the law is unconstitutional on the grounds that the law violates the First Amendment by infringing on protected speech, the law is vague and overbroad, the law is an excessive imposition of the state's policy powers, and the law is preempted by federal law and the comprehensive federal policy governing dietary supplements and their labeling. That litigation is ongoing, with CRN waiting for a decision from the U.S. Court of Appeals for the Second Circuit on a preliminary injunction appeal.[9]

II. Dietary Supplements are Extensively Regulated by the Federal Food and Drug Administration (FDA)

The FDA is the primary federal agency responsible for overseeing dietary supplement safety, manufacturing, labeling, and other practices under the Food, Drug, and Cosmetic Act (FDCA) as amended by the Dietary Supplement Health and Education Act (DSHEA). In regulating dietary supplements, the FDA protects "the public by identifying and removing unsafe and illegal [dietary supplements] from the market," ensuring that dietary supplements are safe, well-manufactured, and accurately labeled.

Dietary supplements are subject to stringent regulatory requirements, under FDA oversight, including the following:

(1) Mandatory notification to FDA for ingredients introduced to the market after DSHEA's passage, with the notification accompanied by evidence that the ingredient is "reasonably expected to be safe";[10]

[7] New York Association of Convenience Stores, MEMORANDUM OF OPPOSITION, S. 5823 (Mayer)/A. 5610 (Rozic)
[8] *Id.*
[9] Brief and Special Appendix for Plaintiff-Appellant, *Council for Responsible Nutrition v. James*, No. 24-1343 (2d Cir. July 3, 2024).
[10] 21 U.S.C. § 350b.

(2) Comprehensive Good Manufacturing Practices (GMPs), which are enforced through FDA inspections;[11]
(3) Labeling requirements[12] that include mandatory disclosure of all ingredients, notice requirements to FDA for claims made on the labeling,[13] limits on the nature of claims that can be made for these products,[14] and substantiation requirements for claims made for the product;[15]
(4) Mandatory recordkeeping of adverse events and a 14-day window for reporting to FDA of serious adverse events, which act as further post-market surveillance on the market for potential signals of safety risks; and
(5) Further, provisions of the federal law regarding adulterated or misbranded dietary supplements provide FDA with the authority to seize, detain or recall violative products.[16]

III. New York's Law is Preempted by Federal Law and the Comprehensive Federal Policy Governing Dietary Supplements and Their Labeling

The New York law is expressly preempted by the FDCA. The FDCA contains an express preemption clause, whereby Congress explicitly preempted any requirements imposed on the ability to make structure/function claims which differ from those in the FDCA. In barring the sale of dietary supplements to minors based solely on the statements made in their labeling, the New York legislature has overridden the express interest of Congress, who carefully crafted a federal-level regime to ensure consumer access to important health information and products that New York is now attempting to restrict.

The FDCA expressly regulates a dietary supplement company's ability to make claims about the "role of a nutrient or dietary ingredient with respect to the structure or function of the human body," referred to as structure/function claims.[17] To make such a claim, the federal framework provides a list of criteria that must be met – (1) the manufacturer must be able to substantiate that the claim is truthful and not misleading; (2) the claim is limited to describing effects on the structure/function of the body and not state or imply that the product can treat disease; and (3) the claim must be accompanied by both a disclosure notifying consumers that FDA has not evaluated the claim and the product is not intended to treat a disease, and notification to the FDA of the claim.[18] The "weight-loss" and "muscle-building" claims that New York is attempting to restrict by attaching sales limitations to the use of the claim are structure/function claims subject to the FDCA's express preemption provisions.[19]

The FDCA prohibits states from "directly or indirectly" establishing any labeling requirement that is not "identical to" the FDCA section 343(r)(1) requirements (of which the structure/function claim

[11] 21 C.F.R. Part 110 and 117.
[12] 21 C.F.R. § 101.36.
[13] 21 U.S.C. § 343(r)(6).
[14] *Id.*
[15] *Id.*
[16] 21 U.S.C. § 334 and 21 U.S.C. § 3501.
[17] 21 U.S.C. § 343(r)(6)(A).
[18] 21 U.S.C. § 343(r)(6).
[19] *See, e.g., Ferrari v. Vitamin Shoppe Indus. LLC,* 70 F.4th 64, 70 (1st Cir. 2023) (permissible structure/function claims include statements that product "helps increase muscle size," "enhance muscle tone," and "helps support muscle growth"). Similarly, the FDA permits statements about weight loss as appropriate structure/function claims. *See,* 65 Fed. Reg. 999, at 1027 ("FDA believes that the legislative history in fact supports FDA's view that weight loss claims are properly considered structure/function claims").

requirements are a part).[20] A state requirement is "not identical" where "the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition of labeling of food" that "[a]re not imposed by or contained in the applicable provision" or that "[d]iffer from those specifically imposed by or contained in" the FDCA and its implementing regulations.[21] As a result of the FDCA preemption provision, there "are only two ways" in which a state "may escape its preemptive force."[22] Specifically, a law is preempted unless it (1) imposes "requirements that are identical to those imposed by the FDCA"; or (2) the state law requirements "are not with respect to claims of the sort described in Section 343(r)(1)."[23]

The New York law does not fall into those exceptions and it runs directly afoul of the FDCA's preemption provision by imposing requirements on the use of certain structure/function claims in labeling in a manner that differs from the requirements imposed by or contained in the federal law. Both the FDCA and the New York law regulate structure/function claims by imposing requirements that must be met if an entity wants to use a structure/function claim on their labeling. Federal law requires substantiation and disclosure of qualifying information/FDA notification, and prohibits claims about disease treatment. The New York law adds an additional requirement to the use of certain structure/function claims – i.e., using "weight-loss" and "muscle-building" structure/function claims in New York requires an entity to limit sales to consumers over the age of 18 and enact age-verification systems as part of the sales transaction. These requirements imposed on structure/function claims in New York are different from the federal scheme and, thus, preempted.[24]

Ultimately, "the purpose of Congress is the ultimate touchstone in every pre-emption case."[25] By imposing additional sales restrictions on legal, federally regulated labeling claims, New York has upended core purposes of Congress in enacting DSHEA. For example, a key purpose behind DSHEA was to eliminate the erection of "barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements and to clarify that dietary supplements are not drugs . . . and should not be regulated as drugs."[26] The New York law defies this purpose – it makes it more difficult for consumers to purchase dietary supplements, obstructs the free-flow of accurate information about dietary supplements which the federal government already comprehensively regulates, wholly bars minors from purchasing otherwise legal products, and in some ways regulates dietary supplements to a greater extent than drugs, which minors may purchase in many circumstances without restriction.

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We appreciate the opportunity to comment and the DOJ's consideration of this issue. We ask that the DOJ consider taking action to notify the state of New York of the preemptive effect of the law or other

[20] "Structure/function claims under § 343(r)(6) fall within § 343(r)(1)'s ambit." *Ferrari,* 70 F.4th. at 68.
[21] 21 C.F.R. § 100.1(c)(4)
[22] *Ackerman v. Coca-Cola Co.*, No. CB-09-0395 (JG), 2010 WL 2925955 (E.D.N.Y. July 21, 2010).
[23] *Id.*
[24] *Greenberg v. Target Corp.,* 985 F.3d 650, 656 (9th Cir. Jan. 13, 2021) ("[I]f the defendants' [product description] meets the FDCA's three requirements for a structure function claim, than any state law claims challenging that claim fall to the wayside").
[25] *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).
[26] *Ferrari,* 70 F.4th at 73 ("If the manufacturer's label satisfies [federal] requirements, consumers may not attack the structure/function claim under state law").

action as appropriate to preserve the comprehensive federal framework governing dietary supplements and the health information disseminated about them. We would welcome a meeting to further discuss this issue.

Sincerely,

Megan Olsen
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