



June 6, 2023

The Honorable Kathy Hochul
Governor
State of New York
NYS Capitol Building
Albany, New York 12224

Re: A5610D/S5823C—An act to add Section 391-00 to the general business law in relation to establishing restrictions on the sale of over-the-counter diet pills and dietary supplements for weight loss or muscle building

Dear Governor Hochul,

We write in connection with A5610D/S5823C, which passed both houses of the New York legislature. Founded in 1936, the Natural Products Association (NPA) is the oldest and largest trade association representing the natural products industry. It represents over 700 diverse member organizations united in providing consumers with access to safe products to maintain and improve their health. NPA has taken a leadership role in promoting quality standards and has developed proactive certification programs. For example, NPA was the first organization to offer a third-party good manufacturing practices (GMP) certification program to dietary supplements and ingredient manufacturers. NPA's GMP standards include the FDA's requirements of 21 C.F.R. Part 111 and specific requirements that exceed Part 111 or reflect best industry practices.

Since 2014, I have led the organization as its president and CEO. Before joining NPA, I served as the top enforcement official at the Food and Drug Administration's Division of Dietary Supplements during the Obama Administration. My tenure at FDA is considered one of the most productive enforcement periods in the FDA's modern history averaging approximately 15 legal actions annually and more than 200 administration actions per year.

I am writing to you with grave concerns regarding the passage of A5610D and the implementation and enforcement of the legislation. As you may know, A5610D would prohibit the sale of dietary supplements marketed for muscle building or weight loss to consumers under 18 without a prescription and establishes a series of restrictive limitations. You vetoed similar legislation S-16 (enclosed) from the last session of the legislature. In reviewing the veto letter, the changes to the legislation have not addressed your concerns. We'll point out those specifics in the following communication with your office.

More troubling and urgent is that this legislation is so poorly constructed that it imposes additional requirements on dietary supplements making structure/function claims than what is already provided by the Federal Food Drug and Cosmetic Act ("the Act") and the code of federal

regulations (“CFR”). Specifically, the Act expressly preempts any state law that establishes “*any requirement respecting any claim of the type described in section 343(r)(1) ... made in the label or labeling of food that is not identical to the requirements of section 343(r) of this title.*” 21 U.S.C. § 343-1(a)(5).

Contrary to the misstatements that dietary supplements aren’t regulated by the FDA, the FDA imposes a number of requirements for structure/function claims on dietary supplements. 21 U.S.C. §§ 321(g), 343(r)(1)(A), (r)(6); 21 CFR § 101.93. Two are relevant here: (1) The manufacturer must have substantiation that the statement is truthful and not misleading, and (2) the statement must not claim to “diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.”

The distinction between structure/function and disease claims is extremely important because disease claims require prior approval by the FDA, and making an unauthorized disease claim can render the product a misbranded, unapproved “drug.” See 21 C.F.R. § 101.93(g).

In addition to the statute, case law has also held that legitimate structure/function claims fall under the FDCA’s preemption umbrella (Dachauer, 913 F.3d at 847).

New York State has now passed legislation that is intent on new requirements that restrict products from making specific structure/function claims and/or restrict access to products based on the structure/function claims that are being made on those products. None of these proposed requirements follow the statutory requirements cited above for structure function claims or 21 CFR § 101.93 that established which claims, specifically disease claims, are prohibited/restricted from interstate commerce by FDA. As these proposed requirements aren’t identical to the provisions governing structure/function claims, such proposals would be preempted by the Act.

Given this matter on commercial speech and other issues, A5610D should be vetoed. NPA would be happy to discuss this matter with you or answer any questions.

Thank you,

A handwritten signature in black ink, appearing to read "Dan Fabricant", is enclosed in a thin black rectangular border.

Daniel Fabricant, Ph.D.
President and CEO
Natural Products Association

cc: Dr. Mary T. Bassett, Commissioner, NYS Department of Health
Stacy Lynch, Chief of Staff, Office of the Governor
Laura Mascuch, Chief of Staff, NYS Department of Health