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February 7, 2024

VIA ECF
Hon. Joan M. Azrack
United States District Court for the Eastern District of New York
Long Island Courthouse
100 Federal Plaza
Central Islip, NY 11722

Re: NATURAL PRODUCTS ASSOCIATION v. JAMES, LETITIA
Docket No.: 2:23-cv-08912 (Azrack, J.) (Dunst, M.J.)

Dear Judge Azrack:

Our firm represents Natural Products Association ("NPA") in the above-referenced action and writes this letter in response to Defendant Letitia James's letter dated January 31, 2024, pursuant to which Defendant requested a pre-motion conference to be scheduled regarding Defendant's anticipated motion to dismiss NPA's Complaint. NPA's Complaint seeks judgment, among other things, that New York's Assembly Bill A5610 (to be enacted as NY Gen. Bus. Law § 391-oo) is unconstitutional as preempted by federal law, void for vagueness, and violative of the dormant commerce clause. The Act purports to regulate certain "over-the-counter diet pill or dietary supplement is labeled, marketed or otherwise represented for the purpose of achieving weight loss or muscle building" (the "Covered Supplements"). Not only is the Act unconstitutional as set forth in the Complaint, but there has never been any causal link between the Covered Supplements and eating disorders, so there is no cognizable logic for its implementation in the first place. On January 31, 2024, Defendant filed her motion for a pre-motion conference (Dkt. No. 13) seeking leave to brief potential dismissal of NPA's claims. In her letter, Defendant avers that the Complaint should be dismissed because (1) NPA lacks standing and its suit is not ripe, (2) the Act (as defined in Defendant's letter) is not expressly or impliedly preempted, (3) the Act does not violate the dormant commerce clause and (4) the Act is not void for vagueness. Defendant's arguments fail for at least four reasons.

First, NPA has standing because the Complaint alleges that the Act will imminently and directly affect members of NPA that sell and market supplements in New York on a daily basis. As alleged in the Complaint, NPA is a nonprofit organization representing "over 700 member organizations, accounting for more than 10,000 retail, manufacturing, wholesale and distribution locations of natural products, including . . . dietary supplements. [NPA] unites a diverse membership from the smallest health food store to the largest dietary supplement manufacture." Compl. ¶ 11. Therefore, unlike the plaintiff in *Faculty, Alumni & Students Opposed to Racial Preferences v. New York Univ.*, 11 F.4th 68 (2d Cir. 2021) who failed to allege when and if its members were participating in the conduct subject to regulation, NPA's Complaint sufficiently alleges that its members are in the relevant market and are actively selling dietary supplements to the general public every single day. There is no requirement that NPA "name names" of its members to satisfy the standing

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requirement. *Id* at 76; *see also Bldg. & Const. Trades Council of Buffalo, New York & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138 (2d Cir. 2006). Moreover, since NPA's members are already engaged in the conduct sought to be regulated by the Act (i.e., the sale of dietary supplements), if NPA's members do not change the way they currently conduct their business (i.e., by implementing age-verification systems for both in-store purchases and online purchases), they will necessarily be subject to prosecution under the Act, as the Act specifically grants Defendant the power to prosecute anyone who sells dietary supplements or diet pills to anyone under the age of eighteen. *See Brooklyn Branch of Nat'l Ass'n for Advancement of Colored People v. Kosinski*, 657 F. Supp. 3d 504, 517 (S.D.N.Y. 2023), citing *Babbitt v. United Farm Workers Nat. Union*, 442 U.S. 289 (1979)(when a plaintiff seeks review of law prior to its enforcement, they can establish injury through a plausible allegation of their intention to engage in the conduct prohibited by the law for which there exists a credible threat of prosecution); *Hedges v. Obama*, 724 F.3d 170, 197 (2d Cir. 2013)(courts are "quite forgiving" to plaintiffs seeking pre-enforcement review and are "willing to presume that the government will enforce the law ... in the absence of a disavowal by the government or another reason to conclude that no such intent existed"); *see also Holder v. Humanitarian Law Proj.*, 561 U.S. 1, 16, 130 S.Ct. 2705 (2010) (emphasizing that "the Government has not argued ... that plaintiffs will not be prosecuted if they do what they say they wish to do" in analysis of pre-enforcement standing). Therefore, NPA, an organization whose members are directly involved in the sale the Covered Supplements to the general public, has standing to sue on behalf of its members who are likely to face inevitable (even if unfounded) prosecution under the Act in spite of the immediately necessary monetary resources they will expend in seeking compliance with the Act (i.e., injury-in-fact). Compl. ¶ 60-64. Consequently, NPA has standing for at least the reasons stated above.

Second, as alleged in the Complaint, the Act is preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"). Compl. ¶ 24-30 and 36-42. The Act sets forth several factors to be used by New York courts when determining whether "an over-the-counter diet pill or dietary supplement is labeled, marketed or otherwise represented for the purpose of achieving weight loss or muscle building" and therefore considered a dietary supplement or diet pill under the Act. By creating this new definition, the Act effectively creates a new category of dietary supplement under New York law, which establishes particular requirements related to the Covered Supplements and departs from the expressly mandated boundaries of FDCA. In New York, this means that a product could be regulated differently based on the product's label or marketing depending upon whether it is marketed in New York or outside of it.

The Act then gives third parties authorization to bring a private right of action for any purported violations regarding the sale of products determined to be a Covered Supplement, which can arise under the Act's vague new rubric. The Act's new categorization of certain types of dietary supplements conflicts with the definition and enforcement provisions of the FDCA—acts that are expressly preempted by the FDCA—and prohibited for at least this reason. Furthermore, New York contends that, its label change requirement is only implicit, when it is hard to imagine any other outcome that could conceivably arise from the Act. The unavoidable requirement to modify product labels flows directly from the express terms of the Act, which causes this situation to differ

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from the cases cited by Defendant. Accordingly, the Act is expressly preempted and gives rise to circumstances when implicit preemption could and should apply given the impropriety of the Act's mandates.

Given the Act's attempt at preempting the FDCA—either explicitly or implicitly under these circumstances—NPA's Complaint would survive any dismissal motions on this issue.

Third, the Act violates the Dormant Commerce Clause. This violation arises most apparently in two scenarios. First, by imposing massive hurdles for national manufacturers, retailers, and brands to adhere to New York's vague and improper Act. Second, it improperly favors brick-and-mortar retailers that are physically located in New York over online retailers located across the country. As alleged in the Complaint, the effect of the Act will force online retailers to either halt all online sales to the State of New York or expend extreme costs in ensuring that products ordered online are hand-delivered to ID-bearing New York customers to ensure the age of the recipient of the product, which presents a myriad of logistical and pragmatic considerations that make the Act facially overburdensome. Compl. ¶ 55-61. Indeed, while certain delivery companies have mechanisms to handle sales to individuals over the age of 21, there has been no demonstration by Defendant that such mechanisms exist for those under the age of 18 for the purposes of the Act. There is no apparent way that New York's Act could not offend the Dormant Commerce Clause, and its telling that Defendant identifies no mechanisms that could allow market actors to adhere to the onerous and nonsensical provisions.

Fourth, the Act is void for vagueness because it creates an entirely new definition of a type of dietary supplement that conflicts with the FDCA while also failing to define certain terms, such as "weight loss" and "muscle building." Compl. ¶ 58. The Act neither defines "weight loss" nor "muscle building" or explains how these relate to, or are subsumed by, the definitions within FDCA. The ill-phrased Act creates confusion regarding what will and will not be considered a regulated dietary supplement or diet pill under the Act and will lead multiple interpretations of the same by courts and the people and entities that are prosecuted under the Act (who very well may believe they are in compliance with the Act).

For at least the foregoing reasons, NPA requests that this Court deny Defendant's request for a formal briefing schedule, particularly as it relates to the tenuousness of Defendant's arguments and the looming harm to NPA's members, which should be delt with imminently to foreclose enaction of this Act. Should Defendant choose to move forward with its request to submit a motion to dismiss NPA's Complaint, NPA objects to the 45-day timeline proposed by Defendant in their letter due to the harm that will be incurred in the interim.

Respectfully,

/s/ Kevin M. Bell

Kevin M. Bell

cc: Counsel for Defendant via ECF