STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

LETITIA JAMES
ATTORNEY GENERAL

DIVISION OF REGIONAL OFFICES
SUFFOLK REGIONAL OFFICE

January 31, 2024

Hon. Joan M. Azrack
United States District Court for the Eastern District of New York
100 Federal Plaza
Central Islip, N.Y. 11722

Re: **Natural Products Association v. James**
Docket No.: 2:23-cv-08912 (Azrack, J.) (Dunst, M.J.)

Dear Judge Azrack:

This Office represents Defendant Letitia James, sued in her official capacity as Attorney General of the State of New York ("AG James"), in the above-referenced action, and writes to request that a pre-motion conference be scheduled regarding the anticipated filing of a motion to dismiss the Complaint under F.R.C.P 12(b)(1) & (6). Should the Court decide that a pre-motion conference is not necessary, Defendant respectfully requests that the Court set a briefing schedule providing at least 45 days in which to make her motion.

Background

In this action, National Products Association ("Plaintiff"), a nonprofit organization allegedly representing 700 members which sell, manufacture, and distribute, among other things, dietary supplements, brings a pre-enforcement facial challenge to the constitutionality of New York's Assembly Bill A5610, effective April 22, 2024 (to be codified at NY Gen. Bus. Law § 391-oo, collectively referred to as the "Act"). The Act was enacted to address adolescent eating disorders, and prohibits vendors from selling, offering to sell, or giving away over-the-counter diet pills or a certain category of dietary supplements—i.e., those that are labeled, marketed, or represented as achieving weight loss or muscle building—to minors. *See* Act, § 2. The Act, however, does not affect or regulate the contents on labels for dietary supplements; and indeed, the term "dietary supplement" is defined as a product labeled as such under federal law. *See* Act § 1(a); § 391-o(2)(a)(3). If there is a potential violation of the Act, AG James has the discretion to seek an injunction, *id*. at § 5, and if a court believes, based upon a consideration of various specified factors, *id*. at § 6, that a product is "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building," it may issue an injunction or up to $500 in penalties, *id*. at § 5.

Plaintiff alleges that the Act is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et. seq.* Specifically, it alleges that: (1) the FDCA expressly preempts the Act under 21 U.S.C. § 343-1(a)(5); (2) the Act's definition of "dietary supplements" and the above-referenced factors the court is required to consider in determining whether a product is labeled, marketed, or otherwise represented as being for weight loss or muscle building conflict with the FDCA's definition of dietary supplement under 21 U.S.C. § 321(ff); and (3) by allowing for enforcement actions, the Act conflicts with

the FDCA's prohibition on private rights of action. *See* 21 U.S.C. 337(a). The Complaint also claims that the Act is impliedly preempted by the FDCA.

In addition, Plaintiff asserts a purported violation of the Dormant Commerce Clause, alleging that the Act, "both facially and in effect," discriminates against out-of-state dietary supplement vendors and buyers. Finally, the Complaint conclusorily alleges that the Act is void for vagueness, presumably under the Due Process Clause. As relief, Plaintiff seeks a declaration that the Act is unconstitutional and an injunction precluding AG James from enforcing or otherwise bringing suit under the Act.

The Complaint is both jurisdictionally and substantively defective, as discussed below.

Plaintiff Lacks Standing to Sue. Although Plaintiff brings this action in its "representative capacity," Compl., ¶15, it lacks associational standing because it does not sufficiently identify at least one member who has suffered or would suffer harm as a consequence of the Act or any action by AG James. *See Faculty, Alumni, & Students Opposed to Racial Preferences v. N.Y. Univ.*, 11 F.4th 68, 76-78 (2d Cir. 2021), *cert. denied*, 142 S. Ct. 2813 (2022) (affirming dismissal on standing grounds because membership association failed to identify any member who suffered the requisite harm); *Art & Antique Dealers League of Am. v. Seggos*, 2019 U.S. Dist. Lexis 16620, *6 (S.D.N.Y. Feb. 1, 2019) (same).

Relatedly, Plaintiff has not sufficiently alleged an injury that is certainly impending or substantially likely to occur so as to constitute the requisite injury-in-fact. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Instead, Plaintiff's "injury" is merely a fear of future harm; *i.e.*, the possibility that unidentified members may be subjected to lawsuits and/or fines if they violate the Act in an unspecified way with an undescribed product, *see* Compl., ¶¶60, 61, 62; and/or harm that is not concrete or particularized, *i.e.*, having to incur "undefined," "extreme" costs at some unspecified time to comply with the Act's straight-forward age verification requirement, *id*. at ¶¶62-63. Such harm is insufficient for standing. *See Kimmel v. N.Y. State Assembly*, 2020 U.S. Dist. Lexis 198369, *5-6 (E.D.N.Y. Oct. 26, 2020) (plaintiff had no concrete and particularized injury fairly traceable to implementation of challenged law).

Plaintiff's Suit is Not Ripe. Plaintiff's speculative concerns about the Act and future harm also means that there is no justiciable controversy ripe for this Court's review. *See, e.g., New York State Vegetable Growers Ass'n v. Cuomo*, 2021 U.S. Dist. Lexis 101865, *12-16 (W.D.N.Y. May 27, 2021), *adopted by*, 2021 U.S. Dist. Lexis 120157 (W.D.N.Y. June 28, 2021) (pre-enforcement challenge to state law was not ripe where plaintiffs failed to offer anything more than speculation that unfair prosecution might occur in the future).

The Act is Not Expressly Preempted. The FDCA, through the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq.*, expressly precludes states from imposing, directly or indirectly, any labeling requirement that is not identical to the federal requirement. 21 U.S.C. § 343-1(a)(5). This provision has no application here, however, because the Act does not impose any new or different labeling requirement on any products sold by dietary supplement vendors. Instead, as described above, it is a sales regulation—one that simply prohibits sales of a class of dietary supplements to minors. *See*, *e.g.*, *Jovel v. I-Health, Inc*., 2013 U.S. Dist. Lexis 139661, *8 (E.D.N.Y. Sept. 27, 2013) (purpose of NLEA preemption provision is to prevent States from adopting inconsistent requirements regarding **labeling** of nutrients).

Moreover, there is no conflict between the Act and the FDCA's definitional section of "dietary supplement." As mentioned above, the Act only applies to dietary supplements labeled as such under the FDCA; meaning, that a product is **only** a "dietary supplement" under the Act if it is **also** labeled as a dietary supplement under the FDCA. Nor do the factors set forth in § 6 of the Act alter or affect the requirements for labeling **on** a dietary supplement's packaging; instead, they only address whether a dietary supplement is "labeled, marketed, or represented for the purpose of achieving weight loss or

muscle building." Thus, there is no conflict preemption. *See, e.g., Hughes v. Ester C Co*., 99 F.Supp.3d 278, 287 (E.D.N.Y. 2015) (no preemption where claim was that company misleadingly marketed dietary supplement). Likewise, the FDCA would not preempt AG James's ability to bring an enforcement action under the Act since any such enforcement action would be focused on whether vendors were violating the ban on selling specified products to minors, rather than on labeling requirements. *See, e.g., FTC v. Quincy Bioscience Holding Co*., 646 F.Supp.3d 518, 530 (S.D.N.Y. 2022) (NY AG's claims, which focused on deceptive advertising—not labeling requirements—were not preempted by FDCA).

The Act is Not Impliedly Preempted. The NLEA precludes reliance on an implied preemption theory. *See N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 123 (2d Cir. 2009) ("The NLEA is clear on preemption, stating that it 'shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. §343-1(a)] of the [FDCA].'"); *see also Holk v. Snapple Bev. Corp*., 575 F.3d 329, 336 (3d Cir. 2009) (same). Even if it could be considered, the Act does not serve as an obstacle to congressional objectives.

There is no Dormant Commerce Clause Violation. The Act does not facially discriminate against interstate commerce because the Complaint does not identify—as it must—any in-state commercial interest that is favored, directly or indirectly, by the Act at the expense of out-of-state competitors. *See Selevan v. N.Y. Thruway Auth*., 584 F.3d 82, 95 (2d Cir. 2009). Instead, all vendors are treated the same, as both in-state and out-of-state vendors are subject to the same prohibitions. *See Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 218 (2d Cir. 2004). Likewise, the Act is not discriminatory in effect because it applies equally to all vendors who sell to minors and does not confer a competitive advantage upon local business vis-à-vis out-of-state competitors. Indeed, Plaintiff purports to challenge the validity of the Act on behalf of in-state retailers as well as out-of-state ones, demonstrating that there is no discrimination on the basis of geography. *See Town of Southold v. Town of E. Hampton*, 477 F.3d 38, 49 (2d Cir. 2007) (noting that the challenged statute did not discriminate in effect since local businesses were also challenging it).

Plaintiff's Void for Vagueness Claim Fails. Plaintiff claims that certain definitions in the Act are undefined ("muscle loss" and "weight building"), making it void, but no plausible facial vagueness challenge has been stated. See *Village of Hoffman Estates v. Flipside, Hoffman Ests., Inc*., 455 U.S. 489, 497 (1982) (a law is facially unconstitutional only if it is "impermissibly vague in all of its applications."). A statute is void for vagueness if it either (1) "fails to provide a person of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or (2) lacks "explicit standards for those who apply it." *Expressions Hair Design v. Schneiderman*, 808 F.3d 118, 142 (2d Cir. 2023). A party pursuing a facial challenge must show that an enactment is "vague not in the sense that it requires a person to conform his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all." *Flipside*, 455 U.S. at 495, n.7. Here, Plaintiff has not alleged, nor could it, that "no standard of conduct" is specified in the Act. And while they assert that there could be potential arbitrary enforcement of the Act because of undefined terms, this is nothing more than pure surmise and speculation.

Respectfully,

Patricia M. Hingerton

Assistant Attorney General

cc: Counsel for Plaintiff via ECF