IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

NATURAL PRODUCTS ASSOCIATION, Plaintiff, v. LETITIA JAMES, in her official capacity as New York Attorney General, Defendant.	)	JURY DEMANDED Case No. 2:23-cv-08912

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff, Natural Product Association ("NPA"), by and through the undersigned counsel, hereby files this First Amended Complaint for Declaratory Judgement and Injunctive Relief against Defendant, New York Attorney General Letitia James, in her official capacity, respectfully showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff is a Delaware non-profit corporation having a principal place of business in Washington, DC.

2. Defendant, Letitia James, is the Attorney General of New York. As the Attorney General of New York, she has been expressly delegated with the authority of enforcing Assembly Bill A5610 (to be enacted as NY Gen. Bus. Law § 391-oo, collectively referred to herein as the "Act"), which specifically states "[w]henever there shall be a violation of [the Act], an application may be made *by the attorney general in the name of the people of the state of New York*, to a court or justice having jurisdiction by a special proceeding to issue an injunction, and upon notice to the

defendant of not less than five days, to enjoin and restrain the continuance of such violation." NY Gen. Bus. Law § 391-oo (emphasis added).

3. The Defendant is subject to the personal jurisdiction of this Honorable Court pursuant to Fed. R. Civ. P. 4(k)(1).

4. This Honorable Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, as it arises under 21 U.S.C. § 301, also known as the Federal Food, Drug, and Cosmetic Act ("FDCA"), thus raising a federal question.

5. This Court has jurisdiction under 28 U.S.C. § 1343(a)(3) because this action, authorized by 42 U.S.C. § 1983, seeks to redress the deprivation, under color of the laws, statutes, ordinances, regulations, customs, and usages of the State of New York and political subdivisions thereof, of rights, privileges, or immunities secured by the United States Constitution and Acts of Congress.

6. Defendant is being sued in her official capacity as Attorney General and, at all relevant times, will be acting under the color of state law. Accordingly, this Court has authority under the doctrine of *Ex Parte Young*, 209 U.S. 123, 28 S. Ct. 441, 52 L. Ed. 714 (1908) to enjoin enforcement of the Act and to grant declaratory relief and injunctive relief pursuant to §§ 2201-02 and 5 U.S.C. §§ 705-06 on the grounds tshat the Act is unconstitutional because it causes, or will imminently cause, ongoing violations of federal law because it (i) void for vagueness and thus violates the Due Process Clause of the Fifth Amendment; (ii) violates the Dormant Commerce Clause; and (iii) is preempted by federal law.

7. Defendant works at and performs her official duties as the Attorney General of New York at the New York State Capitol located on State Street and Washington Avenue, Albany, New York, 12224.

8. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b)(1) because the majority of Plaintiff's New York members' business locations are located within this District.

9. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a) and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

PLAINTIFF'S STANDING

10. Founded in 1936, NPA is the nation's largest and oldest nonprofit organization dedicated to advocating for the rights of consumers to have access to safe products that will maintain and improve their health and for the rights of retailers and suppliers to sell such products.

11. NPA represents over 700 member organizations, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. Plaintiff unites a diverse membership, from the smallest health food store to the largest dietary supplement manufacturer.

12. NPA's members will be adversely affected by the Act.

13. An affidavit identifying and listing at least some of NPA's members that will be adversely affected by the Act is attached as **Exhibit A**.

14. Plaintiff advocates before Congress, the Food and Drug Administration ("FDA"), the Federal Trade Commission, and other federal and state agencies, legislatures, state attorneys' general and courts. Additional information about NPA and its work is available at https://www.npanational.org/.

15. The FDCA directly applies to and affects Plaintiff's members by regulating and prosecuting the sale of dietary supplements.

16. Consequently, Plaintiff has standing to bring this action on behalf of its members in its representative capacity.

BACKGROUND FACTS

17. This dispute arises out of New York's attempt to regulate the sale of dietary supplements, which are a subcategory of food pursuant to U.S. law.

18. On October 25, 2023, New York Governor Kathy Hochul signed Assembly Bill A5610 banning the sale (including internet sales) of over-the-counter weight-loss and sports nutrition supplements to any person under the age of 18. The legislation amends the New York General Business Law and is set to take effect in April 2024 as NY Gen. Bus. Law § 391-oo (collectively defined as the "Act").

19. Section 1(a) of the Act defines a dietary supplement as a class of dietary supplements as defined in NY Gen. Bus. Law § 391-oo, and is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.

20. NY Gen. Bus. Law § 391-oo's definition of dietary supplements differs from the language of § 321(ff) of the FDCA.

21. The Act does not contain the same requirements contained in § 321(ff)(2)(ii) through § 321(ff)(3) of the FDCA.

22. Section 5 of the Act provides a procedure allowing the Defendant to bring a cause of action against a retailer who sells an "over-the-counter diet pill or dietary supplement [that] is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building" as defined by the Act to anyone under the age of 18). The Act states that "[w]henever there shall be a violation of [the Act], an application may be made by the attorney general in the name of the people of the state of New York, to a court or justice having jurisdiction by a special

proceeding to issue an injunction, and upon notice to the defendant of not less than five days, to enjoin and restrain the continuance of such violation." NY Gen. Bus. Law § 391-oo.

23. In addition to enforcement actions by New York's attorney general on behalf of the people of the state of New York, Section 349 of the New York General Business Law provides citizens with the right to bring a private right of action, stating that "[in] addition to the right of action granted to the attorney general pursuant to this section, any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions."

24. But the manufacture, use and sale of dietary supplements in the United States is regulated by the FDCA and enforced by FDA. Private parties are precluded from enforcing the subject matter of FDCA's provisions.

25. Dietary supplements are regulated pursuant to the provisions of the Dietary Supplement Health and Education Act (DSHEA), which amended the FDCA when it into effect on October 15, 1994.

26. The FDCA defines explicitly what types of products are considered dietary supplements. *See, e.g.*, 21 USC § 321(ff).

I. There is No Rational Basis for the Act.

27. Under the FDCA, dietary supplements are considered foods and assumed safe unless FDA has evidence that the supplement or one of its ingredients presents a "significant or unreasonable risk of illness or injury" when used as directed on the label or under normal conditions of use.

28. Neither Congress nor FDA has established a class of dietary supplements for weight loss or muscle building.

29. FDA has not determined or otherwise communicated that the type of dietary supplement products covered by the Act pose a significant or unreasonable risk of illness or injury. If it did, FDA would have already acted to remove those products from the market.

30. FDA has not determined or otherwise communicated that the type of dietary supplement products covered by the Act cause eating disorders, nor has it expressed any related concern.

31. Rather, dietary supplement usage rates—including those that the Act reduces consumer access to—correlate closely with better health outcomes.

32. FDA has not determined or otherwise announced that the scope of products covered by the Act's definition of "dietary supplements for weight loss or muscle building" cause or correlate with eating disorders.

33. Additionally, the NY legislature has not established a correlation, let alone a basis for causation, between the likelihood of developing an eating disorder as a result of using the products covered by the Act's definition of "dietary supplements for weight loss or muscle building."

34. Moreover, to the extent the New York legislature passed the Act in an effort to reduce the likelihood of the incidence of eating disorders in consumers of the products covered by the Act, it is likely that FDA would treat the incidence of eating disorders arising from the use of those products as an adverse event under FDCA. The regulation and oversight of adverse events left exclusively to FDA. The State of New York has never investigated any consumer reports related to eating disorders that were potentially caused by the use of dietary supplements.

35. Regardless, there is also no substantiation that placing dietary supplements behind the counter or restricting their sales to adults could reduce the incidence of eating disorders.

36. The Act also purports to regulate certain "over-the-counter diet pills," which the Act defines as "a class of drugs labeled, marketed, or otherwise represented for the purpose of achieving weight loss that are lawfully sold, transferred, or furnished over-the-counter with or without a prescription pursuant to the [FDCA]."

37. On information and belief, only a single over-the-counter weight loss aid made with the active ingredient "Orlistat" has been approved by FDA, which was specifically approved only for overweight adults.

38. Over-the-counter and prescription versions of Orlistat are approved.

39. Yet the Act's seeks to treat an over-the-counter drug the same as a dietary supplement, thereby imposing the same FDA-defined restrictions for Orlistat products onto a previously unclassified category of dietary supplements. But this improperly collapses the distinctions between the ways dietary supplement are regulated and drugs are regulated. Further, FDA has not restricted a class of "weight loss" or "muscle building" dietary supplements to a particular class of individuals (e.g., overweight adults) nor suggested any such restriction.

40. FDA regulates drugs and dietary supplements differently for many reasons, but one reason for the gatekeeping typically ascribed to drug products is due to the likelihood of side effects associated with their use, which is why the FDCA requires disclosure of potential side effects in drug-product labeling, whereas no such requirement exists or is necessary for dietary supplements.

41. For example, Orlistat's list of potential side effects includes anaphylaxis, increased risk of kidney stones, serious liver problems, increased risk of gallstones, along with gastrointestinal issues.

42. Recently, there has been an increase in the administration of other weight loss drugs to adolescents where those drugs carry significant health risks that are not observed with dietary

supplements. On information and belief, widely publicized drugs like Wegovy, Mounjaru, and Ozempic are being administered to adolescents in the state of New York. But each of these products present the possibility of highly serious side effects not observed with the use of dietary supplements.

43. Wegovy's package insert lists potential side effects that include thyroid tumors (including cancer), gallbladder problems, increased risk of hypoglycemia, kidney failure, serious allergic reactions, increased heart rate, and depression or thoughts of suicide. Wegovy's package insert advises potential users to inform their physician if they previously experienced mental health issues, which would including eating disorders. But neither FDA nor the New York legislature have identified any similar risk of side effects or substantiated any concerns with prior mental health issues related to the dietary supplements covered by the Act.

44. Mounjaru's package insert warns users of the risk of serious side effects including thyroid tumors, along with other side effects that include serious allergic reactions, kidney problems (kidney failure), severe stomach problems, gallbladder problems, and gastrointestinal issues. But neither FDA nor the New York legislature have identified any similar risk of side effects or substantiated any concerns with prior mental health issues related to the dietary supplements covered by the Act.

45. Ozempic's package insert warns users of the risk of thyroid C-cell tumors, pancreatitis, diabetic retinopathy, hypoglycemia with concomitant use of insulin secretagogues or insulin, acute kidney injury, hypersensitivity, acute gallbladder disease, along with gastrointestinal issues. But neither FDA nor the New York legislature have identified any similar risk of side effects or substantiated any concerns with prior mental health issues related to the dietary supplements covered by the Act.

46. Unlike the aforementioned drugs, dietary supplements implicated by the Act do not carry the risk of such severe side effects and are intended to be used to maintain healthy conditions in users. The Act will reduce access for health-promoting dietary supplements that help to improve the diets and exercise of habits of users, including those in disadvantaged areas reduced access to healthy meal options.

47. Were the state of New York to address the issue of eating disorders head-on, it could do so in a manner less restrictive or more appropriate than the measures set forth in the Act, which has the actual effect of reducing access to products that supplement consumer's diets to complement their overall health.

48. It is apparent that the Act is the improper vehicle to achieve the stated ends. On December 23, 2022, when Governor Hochul vetoed Assembly Bill Number 431-C—the version of the Act introduced but unpassed in a prior legislative session—the Honorable Governor stated the following about the legislation's enaction:

> This legislation would require the Department of Health (DOH) to determine what products should be limited under this new law. DOH does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA. Without sufficient expertise, DOH is not equipped to create a list of restricted products. It would also 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.

49. A true and correct copy of the aforementioned veto memorandum is attached as **Exhibit B**.

50. There is and can be no rational basis for the Act.

II. The Act Imposes Undue Burdens and Hardships on the Members of NPA and Violates the Due Process Clause and the Dormant Commerce Clause.

51. Not only does the Act lack any rational basis, but it also imposes undue burdens and harms onto members of NPA.

52. A first example of the type of harm faced by members of NPA is the looming threat of civil penalties from the New York Attorney General or private parties that are imposed by an improperly vague statute.

53. The Act purports to regulate its newly coined category of supplements identified as "dietary supplements for weight loss or muscle building," which Section 1 states to mean "a class of dietary supplement as defined in section three hundred ninety-one-o of this article 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."

54. The Act does not define "weight loss" or "muscle building," or explain how these terms relate to the dietary supplements and over-the-counter diet pills to allow retailers, consumers, or other actors to make sense of the law.

55. Section 6 of the Act sets forth several factors to determine 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."

56. Specifically, Section 6 of the Act states the "court shall consider, **but is not limited to**, the following factors: (a) whether the product contains: (i) an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building; (ii) a steroid; or (iii) creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract; (b) whether the product's labeling or marketing bears statements or images that express or imply that the product will help: (i) modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the

process by which nutrients are metabolized; or (ii) maintain or increase muscle or strength; (c) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle; or (d) whether the retailer has categorized the dietary supplement for weight loss or muscle building by: (i) placing signs, categorizing, or tagging the supplement with statements described in paragraph (b) of this subdivision; (ii) grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store; or (iii) otherwise representing that the product is for weight loss or muscle building." (emphasis added).

57. By merely listing a non-limiting set of factors that could vary depending on circumstances and explicitly leaves the interpretation open to future judicial determinations, the Act does not define what conduct or products are covered by its provisions.

58. The Act also conceived of a new class of dietary supplements without any guidance, precedent, or legal authority that would inform those affected by the Act as to when they are or are not in violation of its provisions. The act simply refers to the undefined terms of "weight loss" or "muscle building," but those terms and the surrounding provisions are vague enough that the Act could conceivably require age-verification to purchase foods that have been consumed by humans for hundreds of years.

59. Thus, it would be unfair to expect NPA members to determine which products they can and cannot sell over-the-counter to minors, particularly while facing the threat of civil penalties.

60. A second type of harm faced by NPA members arises from the efforts put forth to comply with the technical and logistical hurdles to accommodate the Act's requirements, along with the associated severe economic burden. Members located outside of New York are harmed

more by this type of harm than those located inside the state of New York. Thus, the Act is facially discriminatory or discriminatory in effect because it improperly favors in-state actors over out-of-state actors.

61. The disproportionate harm to out-of-state entities compared to in-state entities can arise in many ways, but a particular example helps illustrate this scenario. Under the Act, an out-of-state actor that sells to consumers in New York must establish an age-verification process capable of verifying that the recipient of any covered dietary supplement is over 18 years of age.

62. As of now, on information and belief, no applicable age-verification process exists to satisfy the Act's age-verification of 18-year-olds.

63. Consequently, an entity residing outside of New York will need to establish its own delivery service or establish the logistical and technical framework to ensure that national delivery service providers are adhering to the age-verification requirements set forth in the statute.

64. While, on the other hand, in-state actors, such as brick-and-mortar locations likely face a much more straightforward route with complying with the law by enacting protocols to verify age during a face-to-face transaction, which in many instances, would require nothing more than a person simply eyeballing a piece of identification physically presented to them.

65. The disparity of hardships associated with face-to-face transactions occurring at in-state retail locations and online sales occurring with out-of-state entities becomes even more apparent as various inevitable scenarios are considered.

66. For example, each and every time a delivery service provider attempts to deliver a dietary supplement for weight loss or muscle building to a residence at a time when the residence is unoccupied by an adult over the age of 18, the delivery service provider must then retain the products that were to be delivered and then reattempt delivery. In that situation, the delivery service

provider must then reattempt to deliver the products until it is able to arrive at a residence when an 18-year-old is present or otherwise give up and return the products back to the seller.

67. This process would inevitably cause substantial supply chain and logistical disruptions and hardships to such delivery services that must now dramatically increase their delivery capacity to accommodate the many inevitable failed delivery attempts. This scenario thus leads to delivery service providers having to expand their fleet within New York and increase warehouse storage space to house products that are unable to be delivered. It also has the unavoidable and irreversible effect of leading to increased pollution in the form of carbon dioxide emissions, along with the consumption of non-renewable resources like gasoline and hydrocarbons for tires and the like.

68. This process also necessarily requires out-of-state entities to either increase the price of their product when sold and delivered to customers in New York or eat the cost of the additional shipping fees incurred by personal delivery.

69. The economic hardship associated with the foregoing process is severe. The associated economic and logistical impacts would unavoidably inhibit supply chain operation for products beyond the scope of the Act's coverage and limit access of products that New York consumers have used for many years to maintain their health or supplement their diets. Furthermore, these effects are likely to be felt by consumers and entities outside the state of New York via the ripple effects flowing from this supply chain disruption.

70. A further example of this scenario arises for non-New York residents that deliver products to New York residents, without the use of commercial shipping vendors. For example, certain NPA members utilize consultants that facilitate the transaction and delivery of dietary supplements that could be implicated under the Act. They have no distribution centers within the

state of New York and no retail locations within the state of New York, so those members cannot comply with the Act using the same protocols as brick-and-mortar entities positioned within New York, which can more readily verify a customer's age during a face-to-face transaction.

71. While the preceding examples are not an exhaustive list, they are demonstrative of the types harms that arise from an improper and violative statute that should be struck down for the reasons set forth here.

III. The Act is Preempted by the U.S. Constitution's Supremacy Clause or Statutorily Preempted by the FDCA.

72. The concerns and harms arising from the Act are furthered by their departure from and conflict with the provisions of the FDCA and FDA's enforcement mechanisms that are already in place. Indeed, if the issue purportedly solved by the Act were as legitimate as the New York legislature may try to suggest, then surely FDA would have stepped in and regulated the industry under the authority exclusively granted to them by Congress and in light of their decades of experience with these issues.

73. The New York legislature has passed the Act in spite of the fact that the New York Department of Health (DOH) does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA.

74. Without sufficient expertise, DOH is not equipped to create a list of registered products.

75. This is particularly problematic given the Act's conflict with the definition of dietary supplement and related requires as set forth in the FDCA. *See, e.g.*, 21 USC § 321(ff), (ff)(2)-(3).

76. As noted above (*supra* at ¶¶ 51-71), the Act does not define the scope of dietary supplements covered by the Act or how one would determine whether a dietary supplement is for

"weight loss" or "muscle building." The factors in Section 6 of the Act also leave significant ambiguity and create label-change requirements, either explicitly, or implicitly, which then cause the Act to conflict with the FDCA's labeling requirements and dietary supplement definition.

77. The factors recited in Section 6 of the Act also create conflict because Section 6's factors could include prescription drugs that are neither dietary supplements nor over-the-counter drugs pursuant to the rubric of the FDCA.

78. The FDCA includes an express preemption provision that precludes states from imposing, directly or indirectly, any requirement as to the labeling of dietary supplements. *See*, *e.g.*, 21 USC § 343-1(a)(5).

79. Further, 21 USC § 343-1(a)(5) preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements.

80. Section 349 of the New York General Business Law provides citizens with the right to bring a private right of action (*supra* at ¶ 23), but the FDCA prohibits the private enforcement of any of the provisions of FDCA and "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 USC § 337(a).

81. Thus, the Act is either preempted under the Supremacy Clause due to the FDCA's clear mandates prioritizing FDA's regulation of the safety of food and drugs because FDA is vested with that sole enforcement authority and is further expressly preempted by FDCA due to the Act's provisions that conflict or are otherwise superseded by FDCA.

82. Consequently, as set forth herein, the Act is unconstitutional because it causes, or will imminently cause, ongoing violations of federal law because it (i) violates the Due Process Clause as being void for vagueness; (ii) violates the Dormant Commerce Clause; and (iii) is preempted by federal law or the Supremacy Clause of the U.S. Constitution.

COUNT ONE - VIOLATION OF THE DUE PROCESS CLAUSE

83. The preceding paragraphs are incorporated and re-alleged here.

84. The Act violates the Due Process Clause of the Fifth Amendment of the U.S. Constitution.

85. A statute violates the Due Process Clause when it is impermissibly vague, which arises when the statute fails to inform a person of ordinary intelligence a reasonable opportunity to understand what conduct prohibits.

86. The Act's definition of dietary supplements for weight loss or muscle building is impermissibly vague for the reasons set forth in the preceding paragraphs, which would lead to arbitrary and capricious enforcement of its provisions.

87. The Act does not define the class of supplements that are for "muscle loss" and "weight building," and does not instruct NPA members what products are covered by the Act in view of the entirety of the text of the Act and surrounding context.

88. The Act's provisions are impermissibly vague and will lead to arbitrary and capricious enforcement.

89. Since the Act violates the Due Process Clause, it should be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiff with irreparable injury for which there is no adequate remedy at law.

COUNT TWO - VIOLATION OF THE DORMANT COMMERCE CLAUSE

90. The preceding paragraphs are incorporated and re-alleged here.

91. The Commerce Clause, as set forth in Article I, Section 8 of the United States Constitution, expressly grants Congress the power "[t]o regulate commerce with foreign Nations, among the several States, and with the Indian Tribes."

92. The "Dormant" Commerce Clause is inherent in the power granted to Congress under the Commerce Clause and provides that, even if federal law is silent on an area of interstate commerce, states may not enact legislation that directly regulates, discriminates against, and/or impermissibly burdens interstate commerce.

93. The Dormant Commerce Clause prohibits a state from regulating commerce that takes place wholly outside of the state's borders and from punishing a defendant for engaging in conduct that is lawful where it occurs.

94. State laws that are facially neutral violate the Dormant Commerce Clause if their practical effect is to impermissibly burden interstate commerce.

95. To that end, states may not enact legislation that renders unlawful a transaction that occurred wholly out of state, or that controls commerce occurring wholly outside their borders.

96. By regulating the online sale of dietary supplements by any vendor "including online retailers", the Act, burdens interstate commerce in violation of the Dormant Commerce Clause.

97. Specifically, the Act seeks to regulate the conduct of any vendors who may be located outside of the State of New York and sell dietary supplements online to buyers located in New York. Thus, making otherwise lawful conduct unlawful in New York. Theoretically, if other states were to enact laws similar to the Act, it would require dietary supplement vendors to comply with the strictest state restrictions (assuming compliance is even possible), regardless of federal law or the law of the individual state of operation, or face liability. This would allow individual states to establish a national regulatory scheme in violation of the Constitution's delegation of the power to do so to Congress, just as the Act does here.

98. The Act therefore discriminates, both facially and in effect, against out-of-state dietary supplement vendors and buyers in violation of the Dormant Commerce Clause.

99. Further, the Act creates improper anticompetitive harms because it requires stores to check the identification of consumers when they purchase the diet pills in person in the state of New York, but it does not require the same compliance for e-merchants at the time of purchase. On the one hand, it favors e-merchants that themselves do not ship or deliver products that the Act deems an "over-the-counter diet pill or dietary supplement [that] is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building" because those e-merchants are not tasked with ensuring compliance with the Act. The Act imposes restrictions on brick-and-mortar retailers that are physically located in New York by requiring them to, among other things, rearrange their stores to restrict access to the Act's covered products, retrain employees, and face fines at the Defendant's discretion. The Act also favors large businesses that may circumvent the Act's enforcement simply by changing their labels, whereas smaller entities may lack the resources to do so.

100. The Act improperly favors in-state actors over out-of-state actors, as in for example, the comparison of the burdens imposed on vendors shipping products to New York consumers relative to in-state brick-and-mortar locations.

101. In the alternative, the Act imposes a burden on interstate commerce that is clearly outweighed by the putative public benefit.

102. Upon information and belief, representatives involved in the passing of the Act have disavowed the law was passed to combat any legitimate health or safety concerns.

103. As such the burden the statute imposes on interstate commerce as outlined in the preceding paragraphs is clearly outweighed by any purported public benefit.

104. Accordingly, the Act should be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiffs with irreparable injury as stated herein and for which there is no adequate remedy at law.

COUNT THREE – VIOLATION OF THE SUPREMACY CLAUSE

105. The preceding paragraphs are incorporated and re-alleged here.

106. The Supremacy Clause is the source of the preemption doctrine which invalidates state laws that are contrary to federal statutes.

107. Congress expressly and exclusively tasked FDA with enforcing and regulating food and drugs in the manner set forth in the FDCA, precluding the states from enacting laws like the Act's.

108. The FDCA also contains express preemption provisions over state laws that conflict with or otherwise run afoul of the FDCA.

109. The FDCA expressly sets forth the definition of what is legally considered a dietary supplement and the labeling requirements for the same. *See* 21 USC § 321(ff) and 21 USC § 343(r). As such, by redefining how to determine whether or not a product is a dietary supplement based on how the product is "labeled, marketed, or otherwise represented," the Act expressly conflicts with the FDCA.

110. Since the FDCA and the Act are in direct conflict, the FDCA preempts the Act and the Act is unconstitutional.

111. Moreover, the FDCA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in § 343(r)(1) . . . made in the label or labeling of food that is not *identical* to the requirements of § 343(r) of this title." 21 U.S.C. § 343-1(a)(5) (emphasis added).

112. The Act's provisions either expressly require label changes to comply with its provisions (e.g., Section 6(b) of the Act), or implicitly require label changes in a manner that conflicts with the FDCA's labeling provisions, thereby triggering FDCA's preemption.

113. The FDCA also expressly forbids private rights of action. Yet the Act specifically creates a private right of action permitting the Defendant to sue on behalf of its citizens for purported violations regarding the sale of dietary supplements and permits the recovery of monetary damages. This is in direct conflict with Congress's delegation of exclusive enforcement of the FDCA, thereby further demonstrating the Act's preemption by the FDCA.

114. The FDCA expressly preempts the Act in multiple instances. The Act should, therefore, be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiff with irreparable injury for which there is no adequate remedy at law.

115. The FDCA includes an express preemption provision that precludes states from imposing, directly or indirectly, any requirement as to the labeling of dietary supplements. *See, e.g.*, 21 USC § 343-1(a)(5).

116. Further, § 343-1(a)(5) preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements.

117. The FDCA also prohibits the private enforcement of any of the provisions of FDCA and "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 USC § 337(a).

118. However, Section 349 of the New York General Business Law provides citizens with the right to bring a private right of action, stating that "[in] addition to the right of action granted to the attorney general pursuant to this section, any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act

or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions."

119. Thus, New York General Business Law § 349 violates 21 USC § 337(a)'s grant of exclusive enforcement authority to FDA by allowing for private causes of action.

120. Accordingly, the Act should be declared unconstitutional as violating the Supremacy Clause, and its enforcement should be enjoined because it threatens Plaintiffs with irreparable injury as stated herein and for which there is no adequate remedy at law.

121. NPA reserves all rights to modify, amend, or supplement the foregoing as the case proceeds and in the event that issues become elucidated.

INJURY

1. The Act imposes penalties for noncompliance. Any retail seller who fails to comply with the Act is subject to a penalty of up to Five Hundred Dollars ($500) per sale.

2. The Act requires brick-and-mortar retailers located in New York to incur undefined amounts of cost and risk to take preventative measures, including, among other things, rearranging their stores to restrict access to the Act's covered products, retrain employees, and face fines at the Defendant's discretion.

3. The Act allows for private causes of action against purported violators of the Act, thereby subjecting parties to frivolous and numerous lawsuits, unjustly requiring them to defend themselves against claims, whether justified or not.

4. The Act requires out-of-state entities to create and establish mechanisms to ship products to consumers in the state of New York in a manner to comply with the law without a clear or preexisting framework of how to do so.

5. If the Act is not enjoined, Plaintiff's industry members who were previously able to sell products online in the State of New York will be forced to choose between halting all online sales to the State of New York or expending extreme costs in ensuring all products are hand-delivered to New York customers.

6. The Act will cause irreparable harm, including irreparable economic harm to supplement manufacturers, formulators, and distributors if the cost of attempting to comply with the Act's improper terms and provisions exceed the benefit of marketing those products in the state of New York.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests judgment against the Defendant and further Plaintiff prays for:

a. A declaratory judgment that the Act is unconstitutional on its face or, alternatively, as applied to Plaintiffs, because it expressly conflicts with, and is thus preempted by, the FDCA in violation of the Supremacy Clause;

b. A declaratory judgment that the Act is unconstitutional because it discriminates against interstate commerce in violation of the Dormant Commerce Clause, Article I, § 8 of the United States Constitution;

c. An injunctive order restraining Defendant and her officers, agents and employees from enforcing or otherwise bringing suit under the Act;

d. An award of attorneys' fees and costs of suit herein pursuant to 42 USC § 1988, or any other appliable law; and

e. All other, further, and different legal and equitable relief against the Defendant as necessary and appropriate to effectuate the Court's rulings and judgment, and/or as the Court otherwise deems just and equitable.

Respectfully submitted this 1st day of March. 2024.

ARNALL GOLDEN GREGORY LLP

__/s/ Matthew Zapadka_____

Kevin Bell
Maryland Bar No. 14382
Matthew Zapadka
VA Bar No. 88140
Robert Durkin
Richard Cleland

2100 Pennsylvania Avenue, NW
Suite 350S
Washington, DC 20037
(202) 677-4906

April Meeks
171 17th Street NW
Suite 2100
Atlanta, GA 30326
(478) 319-9179

POLSINELLI PC
Aaron E. Zerykier

600 Third Avenue
42nd Floor
New York, New York 10016
(646) 289-6512

Stuart Pape
1401 I Street, NW
Washington, DC 20005

Attorneys for Plaintiff Natural Products Association

CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of March 2024, I caused a true and correct copy of the foregoing First Amended Complaint to be served on all counsel of record via electronic filing in CM/ECF, with notice of case activity to be generated and sent electronically by the Clerk of said Court.

Date: March 1, 2024

/s/ Matthew D. Zapadka
Matthew D. Zapadka